

US3252382 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:13:17

All time stamps listed in this document are displayed in GMT

US3252382

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

[Participant ID](#)

US3252382

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

US3252382

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3252382

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3252382

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3252382

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3252382

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Were any significant conditions reported?

Yes ☒

No ☐

US3252382

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	BREAST CANCER ON LEFT BREAST IN REMISSION
Start date (dd MMM yyyy)	UN MAY 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	25 MAR 2016
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2015
Start Year (derived)	2015
Stop Month and Year (derived)	MAR 2016
Stop Year (derived)	2016

US3252382

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3252382

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3252382

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3252382

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	ADENOMYOSIS
Start date (dd MMM yyyy)	UN JAN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3252382

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN JAN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3252382

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:16 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:16
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	192.2 lb
BMI (<i>xxx.x</i>)	33.06004 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)	

US3252382

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3252382

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*) 29 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN JAN 1990

Date of surgery unknown False

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

Date of last menstruation unknown False

US3252382

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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

INSURANCE AGENT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3252382

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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	

US3252382

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 109869

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 ☒

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Height	ND - Not Done
Weight	ND - Not Done

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:16
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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 (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 12:16
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 11:39

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3252382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 AUG 2020

Collection time (00:00-23:59)

10:59 (24 HR)

Collection date and time (derived)

29 AUG 2020 10:59

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:52	29 AUG 2020 10:52
Nasopharyngeal Swab 2	No		

US3252382

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:26

PC Open Date & Time

29 AUG 2020 11:59

PC Close Date & Time

29 AUG 2020 14:29

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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	29 AUG 2020 19:40
PC Open Date & Time	29 AUG 2020 15:24
PC Close Date & Time	30 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:40

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

01 SEP 2020 12:38

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 SEP 2020 20:53

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

03 SEP 2020 19:11

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:50

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

29 AUG 2020 12:26

PC Open Date & Time

29 AUG 2020 11:59

PC Close Date & Time

29 AUG 2020 14:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

29 AUG 2020 19:43

PC Open Date & Time

29 AUG 2020 15:24

PC Close Date & Time

30 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:41

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:11

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:51

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 12:26
PC Open Date & Time	29 AUG 2020 11:59
PC Close Date & Time	29 AUG 2020 14:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 19:42
PC Open Date & Time	29 AUG 2020 15:24
PC Close Date & Time	30 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

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 ☒

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:08
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 1956

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:41
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 1956

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:38
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 1956

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:54
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 1956

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:10
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

60 of 1956

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:51
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3252382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:11
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 13:49
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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) 26 SEP 2020

What was the treatment time? (00:00-23:59) 13:19 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 13:19

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3252382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 SEP 2020
Collection time (00:00-23:59)	12:54 (24 HR)
Collection date and time (derived)	26 SEP 2020 12:54

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:38	26 SEP 2020 12:38
Nasopharyngeal Swab 2	No		

US3252382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 26 SEP 2020 13:51

PC Open Date & Time 26 SEP 2020 13:39

PC Close Date & Time 26 SEP 2020 16:09

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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 98.1 °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 19:45
PC Open Date & Time	26 SEP 2020 17:04
PC Close Date & Time	27 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 19:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 17:27

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

29 SEP 2020 18:29

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

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

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

01 OCT 2020 18:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

02 OCT 2020 16:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

26 SEP 2020 13:50

PC Open Date & Time

26 SEP 2020 13:39

PC Close Date & Time

26 SEP 2020 16:09

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

26 SEP 2020 19:46

PC Open Date & Time

26 SEP 2020 17:04

PC Close Date & Time

27 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 19:30

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 17:27

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 18:29

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 18:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 16:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 13:49
PC Open Date & Time	26 SEP 2020 13:39
PC Close Date & Time	26 SEP 2020 16:09

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 19:46
PC Open Date & Time	26 SEP 2020 17:04
PC Close Date & Time	27 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

96 of 1956

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:30
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1956

EAB) (1725)

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:27
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 1956

EAB) (1725)

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 18:30
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

102 of 1956

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

104 of 1956

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

		Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 18:28	
PC Open Date & Time	01 OCT 2020 12:00	
PC Close Date & Time	02 OCT 2020 11:59	

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

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 ☒

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 16:48
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3252382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	24 OCT 2020 12:05
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 OCT 2020
Collection time (00:00-23:59)	12:16 (24 HR)
Collection date and time (derived)	24 OCT 2020 12:16

US3252382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:10:18

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 22:12:40

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 09:23:04

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 18:23:20

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 08:13:22

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

25 NOV 2020 12:04:38

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 20:08:12
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

07 DEC 2020 16:17:21

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission 15 DEC 2020 12:46:01

Patient Cloud Open Date & Time 14 DEC 2020 00:01

Patient Cloud Close Date & Time 18 DEC 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 04:07:56

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 00:43:53

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 00:22:20

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 09:39:31

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 06:47:34

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 06:42:09

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:35:19

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 00:21:05
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:55:41

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 15:04:54

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 06:44:36
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 06:25:33
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

15 MAR 2021 07:00:10

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 09:57:47

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

29 MAR 2021 20:52:06

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 07:33:26

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 10:44:54

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 APR 2021 03:39:43
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 00:20:25

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

03 MAY 2021 06:21:36

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	15 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 NOV 2021 23:59
---	-------------------

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	24 DEC 2021 23:59
---	-------------------

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	27 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	31 DEC 2021 23:59
---	-------------------

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2022 00:01
Patient Cloud Close Date & Time	25 FEB 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2022 00:01
Patient Cloud Close Date & Time	08 APR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2022 00:01
Patient Cloud Close Date & Time	19 AUG 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	26 SEP 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	30 SEP 2022 23:59
---	-------------------

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3252382

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:13:17

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		01 MAR 2021 06:45:20

US3252382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments LEFT VOICE MESSAGE.

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

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

Visit date (dd MMM yyyy)	24 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3252382

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	24 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:21 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	24 MAR 2021 13:21
------------------------------------	-------------------

US3252382

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:42:12

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:42:12

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252382

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:13:17

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"/>

US3252382

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:13:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252382

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

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

Visit date (dd MMM yyyy)	9 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3252382

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

Date of updated informed consent (<i>dd MMM yyyy</i>)	9 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	9 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3252382

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

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

US3252382

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 13:24
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 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)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 14:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 11:42:12

Generated On: 09 Jun 2021 16:13:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 MAR 2021

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 13:52

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

US3252382

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	13:44 (24 HR)
Collection date and time (derived)	9 MAR 2021 13:44

US3252382

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 20:08:44

Generated On: 09 Jun 2021 16:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00 - 23:59)	13:44
Collection Date and Time (derived)	9 MAR 2021 13:44

US3252382

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:08:44

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:08:46

Generated On: 09 Jun 2021 16:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252382

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:08:45

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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	OLD29

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 APR 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 09:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 APR 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 10:00
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3252382

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

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.

US3252382

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 APR 2021

What was the treatment time? (00:00-23:59) 09:25 (24 HR)

Treatment Date and Time (derived) 6 APR 2021 09:25

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

US3252382

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 02:05:17

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252382

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252382

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Apr 2021 18:58:08

Generated On: 09 Jun 2021 16:13:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

AEID	USA-US108-2021-MRNA-1273-P30 1000019
Adverse event	ATYPICAL CHEST PAIN
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)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)	13 APR 2021
Hospital Discharge Date (dd MMM yyyy)	15 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 1956

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

ON DAY 36 SAFETY CALL
SUBJECT REPORTED BEING
HOSPITALIZED FOR THE PAST
TWO DAYS. SUBJECT STARTED
WITH SUBSTERNAL CHEST
PAIN AROUND 21:00 ON THE
13TH OF APR 2021. THE
SUBJECT WAS EVALUATED AT
A LOCAL FREE STANDING
EMERGENCY DEPARTMENT
THAT NIGHT. SUBJECT WAS
ADMITTED FOR OBSERVATION
WITH A DIAGNOSIS OF
ATYPICAL CHEST PAIN,
NEGATIVE TROPONINS,
CARDIOLOGY RECOMMENDED
A STRESS TEST, THAT THE
PATIENT UNDERWENT
SHOWING NO REVERSIBLE
ISCHEMIC CHANGES, THE
SUBJECT WAS DISCHARGED
HOME IN STABLE CONDITION
WITH ARRANGEMENT FOR
OUTPATIENT FOLLOW-UP
TODAY THE 15TH OF APR 2021

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)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

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

Yes ☒

No ☐

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

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication ANASTROZOLE

Prophylaxis Yes ☐
No ☒

Indication ESTROGEN CONTROL FOR
BREAST CANCER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1956

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication MENOPAUSE

Dose per administration 37.5

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 1956

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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

TWICE A YEAR

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

PRODUCTION RELEASE (v12.003

352 of 1956

EAB) (1725)

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication CALCIUM SUPPLEMENT

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 1956

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 600

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)

356 of 1956

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication VITAMIN B1

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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)

358 of 1956

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 75

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

360 of 1956

EAB) (1725)

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

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

US3252382

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 20:36:55

Generated On: 09 Jun 2021 16:13:17

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252382

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:13:17

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3252382

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:13:17

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 ☐

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:58:08

Generated On: 09 Jun 2021 16:13:17

SAEID	USA-US108-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:58:08

Generated On: 09 Jun 2021 16:13:17

SAEID	USA-US108-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	16/APR/2021 12:13
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

Audit

US3252382 (Prod: Centex Studies Inc)

US3252382

Form: Participant Creation

Generated On: 09 Jun 2021 16:13:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'US3252382'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:25:39

US3252382

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:25

US3252382

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 AUG 2020'	RWS_ENDPOINT	29 Aug 2020 15:25:40
	ENDPOINT (b) (4)	

US3252382

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[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 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:25

US3252382

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'SCRN'	System	29 Aug 2020 16:13:25

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:25:41

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '58'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'YEARS'	System	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '58'	System	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Female (F)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:13:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:13:47

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Aug 2020'	System	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2020'	System	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Amendment 3 (3)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:04

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	RWS_ENDPOINT	29 Aug 2020 15:25:40
	ENDPOINT (b) (4)	

US3252382

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:13:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'I'	System	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:13:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:30:18
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4)	27 Sep 2020 10:13:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	26 Sep 2020 18:34:28
Coding entries removed.	(b) (4), (b) (6)	26 Sep 2020 18:34:23
User entered 'BREAST CANCER on left breast in remission' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 18:34:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:34:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:33:18
User entered 'Breast cancer'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN May 2015'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '25 Mar 2016'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:32:38
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'May 2015'	System	31 Aug 2020 21:32:38

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2015'	System	31 Aug 2020 21:32:38

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Mar 2016'	System	31 Aug 2020 21:32:38

US3252382

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2016'	System	31 Aug 2020 21:32:38

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:56:13
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'DATA UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:01:11
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:58:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:34:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:34:37
Data point term sent to Coder	System	31 Aug 2020 21:33:19
User entered 'Hysterectomy'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:33:07

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 1990'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:07
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:07
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:07
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 1990'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:07
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:07
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	31 Aug 2020 21:33:07

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	31 Aug 2020 21:33:07

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	31 Aug 2020 21:33:07

US3252382

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	31 Aug 2020 21:33:07

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Per DM CLR: Please update the MH term to reflect if the LUMPECTOMY OF LEFT BREAST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:52:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy (breast cancer) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:39:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:39:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy (breast cancer) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:23:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:23:27
Query 'Per DM CLR: Please update the MH term to reflect if the LUMPECTOMY OF LEFT BREAST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated MH term to reflect indication. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 16:59:59
Data point term sent to Coder	System	06 Nov 2020 16:59:42
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 16:59:31
User entered 'Cancerous LUMPECTOMY OF LEFT BREAST' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 16:59:31

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the MH term to reflect if the LUMPECTOMY OF LEFT BREAST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:11:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 18:36:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Sep 2020 18:36:46
Data point term sent to Coder	System	26 Sep 2020 18:35:29
Coding entries removed.	(b) (4), (b) (6)	26 Sep 2020 18:35:09
User entered 'LUMPECTOMY of left breast' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 18:35:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:35:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	31 Aug 2020 21:35:35
Data point term sent to Coder	System	31 Aug 2020 21:34:19
User entered 'lumpectomy'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 2015'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 2015'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:33:36
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 2015'	System	31 Aug 2020 21:33:36

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2015'	System	31 Aug 2020 21:33:36

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 2015'	System	31 Aug 2020 21:33:36

US3252382

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2015'	System	31 Aug 2020 21:33:36

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 02:45:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 02:45:31
Data point term sent to Coder	System	03 Sep 2020 02:44:45
User entered 'Osteoporosis'	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN UNK 2016'	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	03 Sep 2020 02:44:35
	(b) (4)	

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 2016'	System	03 Sep 2020 02:44:35

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2016'	System	03 Sep 2020 02:44:35

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	03 Sep 2020 02:44:35

US3252382

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	03 Sep 2020 02:44:35

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 15:37:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 15:37:59
Data point term sent to Coder	System	18 Sep 2020 15:37:09
User entered 'menopause'	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN UNK 1990'	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 15:36:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 15:36:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:59
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 15:36:53
User entered empty.	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	18 Sep 2020 15:36:53

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:39:18
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:12:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Haematological and lymphoid tissue therapeutic procedures, HLT: Lymphoid tissue therapeutic procedures, PT: Lymphadenectomy, LLT: Lymphadenectomy - version MedDRA\\23.0.	Coder Import (b) (4)	27 Sep 2020 04:49:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Sep 2020 04:49:37
Data point term sent to Coder	System	26 Sep 2020 18:47:36
User entered 'Lymphadenectomy of upper left extremity'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'un Jan 2015'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'un Jan 2015'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 2015'	System	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2015'	System	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 2015'	System	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '2015'	System	26 Sep 2020 18:46:38

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Adenomyosis, LLT: Adenomyosis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 18:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 18:49:43
Data point term sent to Coder	System	26 Sep 2020 18:48:37
User entered 'Adenomyosis'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'un Jan 1990'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'un Jan 1990'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	26 Sep 2020 18:48:21

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:01:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 15:01:13
User entered 'UTERINE FIBROIDS'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 1990'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 1990'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'Jan 1990'	System	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1990'	System	30 Sep 2020 15:00:26

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '10:16'	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '29 Aug 2020 10:16'	System	31 Aug 2020 21:34:22

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '64' in	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
DataPoint set to visible.	(b) (4) System	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '192.2' lb	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
DataPoint set to visible.	(b) (4) System	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '33.06004'	System	31 Aug 2020 21:34:22
DataPoint set to visible.	System	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'kg/m2'	System	31 Aug 2020 21:34:22
DataPoint set to visible.	System	29 Aug 2020 16:14:11

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'bpm'	System	31 Aug 2020 21:34:22

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'breaths/min'	System	31 Aug 2020 21:34:22

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	31 Aug 2020 21:34:22

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:34:22
	(b) (4)	

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	31 Aug 2020 21:34:22

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09

US3252382

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09

US3252382

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:34:51
	(b) (4)	

US3252382

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:34:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'UN Jan 1990'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:13:17

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:35:51
	(b) (4)	

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 16:16:42
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 16:16:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Insurance agent'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '0'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:13:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:16:17

US3252382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:26

US3252382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Joanna Gurrola Mahoney	29 Aug 2020 16:14:26
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:26

US3252382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'VISIT1'	System	29 Aug 2020 16:14:26

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 AUG 2020'	RWS_ENDPOINT	29 Aug 2020 15:50:53
	ENDPOINT (b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '109869'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:50:53

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:50:53

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:50

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:50

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney	29 Aug 2020 16:14:50
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:50

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:14:50

US3252382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:17

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Nancy Torrence (b) (4)	28 Sep 2020 06:18:23
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:36:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:36:46

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '10:16'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '29 Aug 2020 10:16'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '98.7' F	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '102'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'bpm'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '16'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'breaths/min'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '115'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '80'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:16'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '29 Aug 2020 12:16'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '98.3' F	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '89'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'bpm'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '15'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'breaths/min'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '126'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '82'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:27
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	31 Aug 2020 21:37:27

US3252382

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:37:34
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:37:34
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	29 Aug 2020 16:41:45
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney	29 Aug 2020 16:41:45
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	29 Aug 2020 16:41:45

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 16:41:45

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Joanna Gurrola Mahoney	29 Aug 2020 16:41:45
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '11:39'	Joanna Gurrola Mahoney	29 Aug 2020 16:41:45
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '29 Aug 2020 11:39'	System	29 Aug 2020 16:41:45

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Right Arm (RIGHT ARM)'	Joanna Gurrola Mahoney	29 Aug 2020 16:41:45
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'ONCE'	System	29 Aug 2020 16:41:45

US3252382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 16:41:45

US3252382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:06
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:38:22
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		31 Aug 2020 21:38:22
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:38:22
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 21:38:22
User entered '29 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:38:22
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:38:06
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:38:06
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:38:06
User entered '26 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:38:06

US3252382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '10:59'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:06
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '29 Aug 2020 10:59'	System	31 Aug 2020 21:38:22
User entered '26 Aug 2020 10:59'	System	31 Aug 2020 21:38:06

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '29 Aug 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:43
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:38:43

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:43
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '10:52'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:43
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '29 Aug 2020 10:52'	System	31 Aug 2020 21:38:43

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:38:43

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:43
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:38:43
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered empty.	System	31 Aug 2020 21:38:43

US3252382

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:49
	(b) (4)	

US3252382

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	31 Aug 2020 21:38:49

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:25:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd7996285-2ff4-49e7-a70a-8b956643b1b4'	System	29 Aug 2020 17:26:06
User entered 'Yes (Y)'	System	29 Aug 2020 17:26:06

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:25:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd7996285-2ff4-49e7-a70a-8b956643b1b4'	System	29 Aug 2020 17:26:06
User entered '98.3'	System	29 Aug 2020 17:26:06

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd7996285-2ff4-49e7-a70a-8b956643b1b4'	System	29 Aug 2020 17:26:06
User entered 'No (N)'	System	29 Aug 2020 17:26:06

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:01', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd7996285-2ff4-49e7-a70a-8b956643b1b4'	System	29 Aug 2020 17:26:06
User entered '29 Aug 2020 12:26'	System	29 Aug 2020 17:26:06

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 14:29'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:39:59', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff9c6ccc-649c-4894-8b6b-705db92f31fd'	System	30 Aug 2020 00:40:54
User entered 'Yes (Y)'	System	30 Aug 2020 00:40:54

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:40:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff9c6ccc-649c-4894-8b6b-705db92f31fd'	System	30 Aug 2020 00:40:54
User entered '98.6'	System	30 Aug 2020 00:40:54

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:40:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff9c6ccc-649c-4894-8b6b-705db92f31fd'	System	30 Aug 2020 00:40:54
User entered 'No (N)'	System	30 Aug 2020 00:40:54

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:40:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff9c6ccc-649c-4894-8b6b-705db92f31fd'	System	30 Aug 2020 00:40:54
User entered '29 Aug 2020 19:40'	System	30 Aug 2020 00:40:54

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 15:24'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 2'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '72d1ceed-c74e-4bb0-b738-a73310e97919'	System	30 Aug 2020 17:07:26
User entered 'Yes (Y)'	System	30 Aug 2020 17:07:26

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '72d1ceed-c74e-4bb0-b738-a73310e97919'	System	30 Aug 2020 17:07:26
User entered '98.2'	System	30 Aug 2020 17:07:26

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:18', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '72d1ceed-c74e-4bb0-b738-a73310e97919'	System	30 Aug 2020 17:07:26
User entered 'No (N)'	System	30 Aug 2020 17:07:26

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '72d1ceed-c74e-4bb0-b738-a73310e97919'	System	30 Aug 2020 17:07:26
User entered '30 Aug 2020 12:07'	System	30 Aug 2020 17:07:26

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 3'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '04f0c9be-8182-4686-b7da-9b613e1503a2'	System	01 Sep 2020 00:40:49
User entered 'Yes (Y)'	System	01 Sep 2020 00:40:49

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '04f0c9be-8182-4686-b7da-9b613e1503a2'	System	01 Sep 2020 00:40:49
User entered '98.3'	System	01 Sep 2020 00:40:49

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '04f0c9be-8182-4686-b7da-9b613e1503a2'	System	01 Sep 2020 00:40:49
User entered 'No (N)'	System	01 Sep 2020 00:40:49

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '04f0c9be-8182-4686-b7da-9b613e1503a2'	System	01 Sep 2020 00:40:49
User entered '31 Aug 2020 19:40'	System	01 Sep 2020 00:40:49

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 4'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:06', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a13a6d72-ee16-445d-a27f-2793fac36cd4'	System	01 Sep 2020 17:38:25
User entered 'Yes (Y)'	System	01 Sep 2020 17:38:25

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a13a6d72-ee16-445d-a27f-2793fac36cd4'	System	01 Sep 2020 17:38:25
User entered '97.5'	System	01 Sep 2020 17:38:25

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:18', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a13a6d72-ee16-445d-a27f-2793fac36cd4'	System	01 Sep 2020 17:38:25
User entered 'No (N)'	System	01 Sep 2020 17:38:25

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a13a6d72-ee16-445d-a27f-2793fac36cd4'	System	01 Sep 2020 17:38:25
User entered '01 Sep 2020 12:38'	System	01 Sep 2020 17:38:25

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 5'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:53:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a5df5027-4da8-4ffa-99a6-a547a33c04a5'	System	03 Sep 2020 01:53:50
User entered 'Yes (Y)'	System	03 Sep 2020 01:53:50

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:53:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a5df5027-4da8-4ffa-99a6-a547a33c04a5'	System	03 Sep 2020 01:53:50
User entered '97.6'	System	03 Sep 2020 01:53:50

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:53:41', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a5df5027-4da8-4ffa-99a6-a547a33c04a5'	System	03 Sep 2020 01:53:50
User entered 'No (N)'	System	03 Sep 2020 01:53:50

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:53:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a5df5027-4da8-4ffa-99a6-a547a33c04a5'	System	03 Sep 2020 01:53:50
User entered '02 Sep 2020 20:53'	System	03 Sep 2020 01:53:50

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 6'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '554c5495-1b21-459f-8e83-b4110c97a2e8'	System	04 Sep 2020 00:11:41
User entered 'Yes (Y)'	System	04 Sep 2020 00:11:41

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '554c5495-1b21-459f-8e83-b4110c97a2e8'	System	04 Sep 2020 00:11:41
User entered '97.7'	System	04 Sep 2020 00:11:41

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '554c5495-1b21-459f-8e83-b4110c97a2e8'	System	04 Sep 2020 00:11:41
User entered 'No (N)'	System	04 Sep 2020 00:11:41

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '554c5495-1b21-459f-8e83-b4110c97a2e8'	System	04 Sep 2020 00:11:41
User entered '03 Sep 2020 19:11'	System	04 Sep 2020 00:11:41

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 7'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:08', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '299bac18-d8fa-45cc-ab46-b963c58335bc'	System	04 Sep 2020 17:50:31
User entered 'Yes (Y)'	System	04 Sep 2020 17:50:31

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:14', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '299bac18-d8fa-45cc-ab46-b963c58335bc'	System	04 Sep 2020 17:50:31
User entered '97.4'	System	04 Sep 2020 17:50:31

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '299bac18-d8fa-45cc-ab46-b963c58335bc'	System	04 Sep 2020 17:50:31
User entered 'No (N)'	System	04 Sep 2020 17:50:31

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '299bac18-d8fa-45cc-ab46-b963c58335bc'	System	04 Sep 2020 17:50:31
User entered '04 Sep 2020 12:50'	System	04 Sep 2020 17:50:31

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:05', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e625e864-7e08-459f-82db-fcd3d4faf342'	System	29 Aug 2020 17:26:19
User entered 'None (1)'	System	29 Aug 2020 17:26:19

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:07', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e625e864-7e08-459f-82db-fcd3d4faf342'	System	29 Aug 2020 17:26:19
User entered 'No (N)'	System	29 Aug 2020 17:26:19

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:11', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e625e864-7e08-459f-82db-fcd3d4faf342'	System	29 Aug 2020 17:26:19
User entered 'No (N)'	System	29 Aug 2020 17:26:19

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e625e864-7e08-459f-82db-fcd3d4faf342'	System	29 Aug 2020 17:26:19
User entered 'None (1)'	System	29 Aug 2020 17:26:19

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e625e864-7e08-459f-82db-fcd3d4faf342'	System	29 Aug 2020 17:26:19
User entered '29 Aug 2020 12:26'	System	29 Aug 2020 17:26:19

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 14:29'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:42:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0eb67934-53ea-47d9-a9fa-2c70ddfc117c'	System	30 Aug 2020 00:43:29
User entered 'None (1)'	System	30 Aug 2020 00:43:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:42:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0eb67934-53ea-47d9-a9fa-2c70ddfc117c'	System	30 Aug 2020 00:43:29
User entered 'No (N)'	System	30 Aug 2020 00:43:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:42:57', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0eb67934-53ea-47d9-a9fa-2c70ddfc117c'	System	30 Aug 2020 00:43:29
User entered 'No (N)'	System	30 Aug 2020 00:43:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:43:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0eb67934-53ea-47d9-a9fa-2c70ddfc117c'	System	30 Aug 2020 00:43:29
User entered 'None (1)'	System	30 Aug 2020 00:43:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:43:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0eb67934-53ea-47d9-a9fa-2c70ddfc117c'	System	30 Aug 2020 00:43:29
User entered '29 Aug 2020 19:43'	System	30 Aug 2020 00:43:29

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 15:24'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 2'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:33', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '6b814606-65b8-4da6-a24c-9843c5cea0d6'	System	30 Aug 2020 17:08:17
User entered 'None (1)'	System	30 Aug 2020 17:08:17

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:07:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '6b814606-65b8-4da6-a24c-9843c5cea0d6'	System	30 Aug 2020 17:08:17
User entered 'No (N)'	System	30 Aug 2020 17:08:17

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:01', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '6b814606-65b8-4da6-a24c-9843c5cea0d6'	System	30 Aug 2020 17:08:17
User entered 'No (N)'	System	30 Aug 2020 17:08:17

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:10', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '6b814606-65b8-4da6-a24c-9843c5cea0d6'	System	30 Aug 2020 17:08:17
User entered 'None (1)'	System	30 Aug 2020 17:08:17

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '6b814606-65b8-4da6-a24c-9843c5cea0d6'	System	30 Aug 2020 17:08:17
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 17:08:17

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 3'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61f79b0e-855f-452e-8477-6fb01c2d5911'	System	01 Sep 2020 00:41:25
User entered 'None (1)'	System	01 Sep 2020 00:41:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:40:59', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61f79b0e-855f-452e-8477-6fb01c2d5911'	System	01 Sep 2020 00:41:25
User entered 'No (N)'	System	01 Sep 2020 00:41:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61f79b0e-855f-452e-8477-6fb01c2d5911'	System	01 Sep 2020 00:41:25
User entered 'No (N)'	System	01 Sep 2020 00:41:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61f79b0e-855f-452e-8477-6fb01c2d5911'	System	01 Sep 2020 00:41:25
User entered 'None (1)'	System	01 Sep 2020 00:41:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:23', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61f79b0e-855f-452e-8477-6fb01c2d5911'	System	01 Sep 2020 00:41:25
User entered '31 Aug 2020 19:41'	System	01 Sep 2020 00:41:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 4'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:39:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61829930-9c59-4d52-9eab-5c53ca68543d'	System	01 Sep 2020 17:39:41
User entered 'None (1)'	System	01 Sep 2020 17:39:41

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:39:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61829930-9c59-4d52-9eab-5c53ca68543d'	System	01 Sep 2020 17:39:41
User entered 'No (N)'	System	01 Sep 2020 17:39:41

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:39:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61829930-9c59-4d52-9eab-5c53ca68543d'	System	01 Sep 2020 17:39:41
User entered 'No (N)'	System	01 Sep 2020 17:39:41

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:39:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61829930-9c59-4d52-9eab-5c53ca68543d'	System	01 Sep 2020 17:39:41
User entered 'None (1)'	System	01 Sep 2020 17:39:41

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:39:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61829930-9c59-4d52-9eab-5c53ca68543d'	System	01 Sep 2020 17:39:41
User entered '01 Sep 2020 12:39'	System	01 Sep 2020 17:39:41

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 5'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a26c6857-9c9c-4f7e-8ce0-743bd4a2c7fc'	System	03 Sep 2020 01:54:25
User entered 'None (1)'	System	03 Sep 2020 01:54:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:05', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a26c6857-9c9c-4f7e-8ce0-743bd4a2c7fc'	System	03 Sep 2020 01:54:25
User entered 'No (N)'	System	03 Sep 2020 01:54:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a26c6857-9c9c-4f7e-8ce0-743bd4a2c7fc'	System	03 Sep 2020 01:54:25
User entered 'No (N)'	System	03 Sep 2020 01:54:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a26c6857-9c9c-4f7e-8ce0-743bd4a2c7fc'	System	03 Sep 2020 01:54:25
User entered 'None (1)'	System	03 Sep 2020 01:54:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:23', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a26c6857-9c9c-4f7e-8ce0-743bd4a2c7fc'	System	03 Sep 2020 01:54:25
User entered '02 Sep 2020 20:54'	System	03 Sep 2020 01:54:25

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 6'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e856d045-bceb-4c46-b967-2770aa356172'	System	04 Sep 2020 00:11:15
User entered 'None (1)'	System	04 Sep 2020 00:11:15

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:58', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e856d045-bceb-4c46-b967-2770aa356172'	System	04 Sep 2020 00:11:15
User entered 'No (N)'	System	04 Sep 2020 00:11:15

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e856d045-bceb-4c46-b967-2770aa356172'	System	04 Sep 2020 00:11:15
User entered 'No (N)'	System	04 Sep 2020 00:11:15

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:08', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e856d045-bceb-4c46-b967-2770aa356172'	System	04 Sep 2020 00:11:15
User entered 'None (1)'	System	04 Sep 2020 00:11:15

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:11:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e856d045-bceb-4c46-b967-2770aa356172'	System	04 Sep 2020 00:11:15
User entered '03 Sep 2020 19:11'	System	04 Sep 2020 00:11:15

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 7'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4ac624e5-72f7-4bff-a97d-3c532c6652d2'	System	04 Sep 2020 17:51:03
User entered 'None (1)'	System	04 Sep 2020 17:51:03

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4ac624e5-72f7-4bff-a97d-3c532c6652d2'	System	04 Sep 2020 17:51:03
User entered 'No (N)'	System	04 Sep 2020 17:51:03

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:50', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4ac624e5-72f7-4bff-a97d-3c532c6652d2'	System	04 Sep 2020 17:51:03
User entered 'No (N)'	System	04 Sep 2020 17:51:03

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:50:57', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4ac624e5-72f7-4bff-a97d-3c532c6652d2'	System	04 Sep 2020 17:51:03
User entered 'None (1)'	System	04 Sep 2020 17:51:03

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4ac624e5-72f7-4bff-a97d-3c532c6652d2'	System	04 Sep 2020 17:51:03
User entered '04 Sep 2020 12:51'	System	04 Sep 2020 17:51:03

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:29', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'None (0)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered 'No (N)'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T12:26:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e60c44ee-2a40-4ad1-a1e0-164c797e4ba0'	System	29 Aug 2020 17:26:47
User entered '29 Aug 2020 12:26'	System	29 Aug 2020 17:26:47

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 14:29'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:37', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:41:57', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'None (0)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:42:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered 'No (N)'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-29T19:42:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0a23457d-12d6-4320-a3ef-babf1e5e907f'	System	30 Aug 2020 00:42:12
User entered '29 Aug 2020 19:42'	System	30 Aug 2020 00:42:12

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Aug 2020 15:24'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 2'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'None (0)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered 'No (N)'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-30T12:08:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e6856dd3-d793-4f65-a3ca-fac3048dcdd1'	System	30 Aug 2020 17:08:52
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 17:08:52

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 3'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'None (0)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered 'No (N)'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-08-31T19:41:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'efad755e-5bc0-480b-a663-8a68bb92ae74'	System	01 Sep 2020 00:42:00
User entered '31 Aug 2020 19:41'	System	01 Sep 2020 00:42:00

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 4'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:37', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'None (0)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered 'No (N)'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-01T12:38:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '19a1eb13-41c4-4f42-a814-7989f01321e4'	System	01 Sep 2020 17:38:57
User entered '01 Sep 2020 12:38'	System	01 Sep 2020 17:38:57

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 5'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:30', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'None (0)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered 'No (N)'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-02T20:54:53', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fd41ffc-1292-4131-b7c2-f4342b4261c1'	System	03 Sep 2020 01:54:56
User entered '02 Sep 2020 20:54'	System	03 Sep 2020 01:54:56

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 6'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:29', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:41', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'None (0)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:44', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered 'No (N)'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-03T19:10:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '23ce86db-36ff-4db9-8f58-4cdc1e5ac690'	System	04 Sep 2020 00:10:49
User entered '03 Sep 2020 19:10'	System	04 Sep 2020 00:10:49

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 7'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:05', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'None (0)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:23', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered 'No (N)'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-04T12:51:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f25d5e07-2906-4ee7-9a29-deba7a62cc21'	System	04 Sep 2020 17:51:29
User entered '04 Sep 2020 12:51'	System	04 Sep 2020 17:51:29

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 16:41:45

US3252382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	10 Sep 2020 05:49:52
	(b) (4)	

US3252382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 08:11:40
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SUBJECT VISIT IS WITH IN AS PER PROTOCOL' (Site from System).	Nancy Torrence (b) (4) (b) (4)	10 Sep 2020 05:51:46
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 05:49:52
User entered '9 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	10 Sep 2020 05:49:52

US3252382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	10 Sep 2020 05:49:52
	(b) (4)	

US3252382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	10 Sep 2020 05:49:52
	(b) (4)	

US3252382

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	10 Sep 2020 05:51:59
	(b) (4)	

US3252382

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	10 Sep 2020 05:51:59

US3252382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	17 Sep 2020 04:32:37
	(b) (4)	

US3252382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 20:38:40
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SUBJECT VISIT IS WITHIN WINDOW PERIOD AS PER PROTOCOL' (Site from System).	Nancy Torrence (b) (4)	17 Sep 2020 05:39:40
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 04:32:37
User entered '16 Sep 2020'	Nancy Torrence (b) (4)	17 Sep 2020 04:32:37

US3252382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	17 Sep 2020 04:32:37
	(b) (4)	

US3252382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	17 Sep 2020 04:32:37
	(b) (4)	

US3252382

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	17 Sep 2020 05:39:49
	(b) (4)	

US3252382

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	17 Sep 2020 05:39:49

US3252382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	23 Sep 2020 03:20:42
	(b) (4)	

US3252382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '22 Sep 2020'	Nancy Torrence (b) (4)	23 Sep 2020 03:20:42
	(b) (4)	

US3252382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	23 Sep 2020 03:20:42
	(b) (4)	

US3252382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	23 Sep 2020 03:20:42
	(b) (4)	

US3252382

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	23 Sep 2020 03:20:48
	(b) (4)	

US3252382

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	23 Sep 2020 03:20:48

US3252382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:12:33
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Nancy Torrence (b) (4)	28 Sep 2020 06:12:33
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	28 Sep 2020 06:12:33
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'VISIT2'	System	28 Sep 2020 06:12:33

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:11'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '26 Sep 2020 12:11'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '98.2' F	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '88'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'bpm'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '15'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'breaths/min'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '111'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '78'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '13:49'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '26 Sep 2020 13:49'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '98.5' F	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '86'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'bpm'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '16'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'breaths/min'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '121'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '84'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	28 Sep 2020 06:14:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Nancy Torrence (b) (4)	28 Sep 2020 06:14:59
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	28 Sep 2020 06:14:59
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	26 Sep 2020 18:19:42
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney	26 Sep 2020 18:19:42
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	26 Sep 2020 18:19:42

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 18:19:42

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Joanna Gurrola Mahoney	26 Sep 2020 18:19:42
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '13:19'	Joanna Gurrola Mahoney	26 Sep 2020 18:19:42
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '26 Sep 2020 13:19'	System	26 Sep 2020 18:19:42

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Right Arm (RIGHT ARM)'	Joanna Gurrola Mahoney	26 Sep 2020 18:19:42
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'ONCE'	System	26 Sep 2020 18:19:42

US3252382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 18:19:42

US3252382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:15:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Nancy Torrence (b) (4)	28 Sep 2020 06:15:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:54'	Nancy Torrence (b) (4)	28 Sep 2020 06:15:51
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '26 Sep 2020 12:54'	System	28 Sep 2020 06:15:51

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '26 Sep 2020'	Nancy Torrence (b) (4)	28 Sep 2020 06:16:10
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 06:16:10

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:16:10
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:38'	Nancy Torrence (b) (4)	28 Sep 2020 06:16:10
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '26 Sep 2020 12:38'	System	28 Sep 2020 06:16:10

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 06:16:10

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Nancy Torrence (b) (4)	28 Sep 2020 06:16:10
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	28 Sep 2020 06:16:10
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered empty.	System	28 Sep 2020 06:16:10

US3252382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	28 Sep 2020 06:16:16
	(b) (4)	

US3252382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	28 Sep 2020 06:16:16

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dc6b2a9d-bdef-47c8-a3b8-b95b9d1d0586'	System	26 Sep 2020 18:51:03
User entered 'Yes (Y)'	System	26 Sep 2020 18:51:03

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dc6b2a9d-bdef-47c8-a3b8-b95b9d1d0586'	System	26 Sep 2020 18:51:03
User entered '98.5'	System	26 Sep 2020 18:51:03

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:57', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dc6b2a9d-bdef-47c8-a3b8-b95b9d1d0586'	System	26 Sep 2020 18:51:03
User entered 'No (N)'	System	26 Sep 2020 18:51:03

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:51:01', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dc6b2a9d-bdef-47c8-a3b8-b95b9d1d0586'	System	26 Sep 2020 18:51:03
User entered '26 Sep 2020 13:51'	System	26 Sep 2020 18:51:03

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 13:39'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 16:09'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:03', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f10f25f0-52ba-4017-b04b-a3fa826d1509'	System	27 Sep 2020 00:45:32
User entered 'Yes (Y)'	System	27 Sep 2020 00:45:32

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:10', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f10f25f0-52ba-4017-b04b-a3fa826d1509'	System	27 Sep 2020 00:45:32
User entered '98.1'	System	27 Sep 2020 00:45:32

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:14', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f10f25f0-52ba-4017-b04b-a3fa826d1509'	System	27 Sep 2020 00:45:32
User entered 'No (N)'	System	27 Sep 2020 00:45:32

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f10f25f0-52ba-4017-b04b-a3fa826d1509'	System	27 Sep 2020 00:45:32
User entered '26 Sep 2020 19:45'	System	27 Sep 2020 00:45:32

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 17:04'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 2'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:29:30', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8bb0ecdd-ff45-4737-a83b-aeb767717a42'	System	28 Sep 2020 00:29:48
User entered 'Yes (Y)'	System	28 Sep 2020 00:29:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:29:37', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8bb0ecdd-ff45-4737-a83b-aeb767717a42'	System	28 Sep 2020 00:29:48
User entered '97.3'	System	28 Sep 2020 00:29:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:29:41', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8bb0ecdd-ff45-4737-a83b-aeb767717a42'	System	28 Sep 2020 00:29:48
User entered 'No (N)'	System	28 Sep 2020 00:29:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:29:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8bb0ecdd-ff45-4737-a83b-aeb767717a42'	System	28 Sep 2020 00:29:48
User entered '27 Sep 2020 19:29'	System	28 Sep 2020 00:29:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 3'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:26:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fb90f79-70a5-4b73-8ea3-78e32143709b'	System	28 Sep 2020 22:27:05
User entered 'Yes (Y)'	System	28 Sep 2020 22:27:05

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:26:54', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fb90f79-70a5-4b73-8ea3-78e32143709b'	System	28 Sep 2020 22:27:05
User entered '97.0'	System	28 Sep 2020 22:27:05

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:26:57', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fb90f79-70a5-4b73-8ea3-78e32143709b'	System	28 Sep 2020 22:27:05
User entered 'No (N)'	System	28 Sep 2020 22:27:05

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:03', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '5fb90f79-70a5-4b73-8ea3-78e32143709b'	System	28 Sep 2020 22:27:05
User entered '28 Sep 2020 17:27'	System	28 Sep 2020 22:27:05

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 4'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:28:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '18078df4-bd0c-4a46-85d0-3b17ba7b63c0'	System	29 Sep 2020 23:29:16
User entered 'Yes (Y)'	System	29 Sep 2020 23:29:16

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:28:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '18078df4-bd0c-4a46-85d0-3b17ba7b63c0'	System	29 Sep 2020 23:29:16
User entered '97.8'	System	29 Sep 2020 23:29:16

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:10', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '18078df4-bd0c-4a46-85d0-3b17ba7b63c0'	System	29 Sep 2020 23:29:16
User entered 'No (N)'	System	29 Sep 2020 23:29:16

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '18078df4-bd0c-4a46-85d0-3b17ba7b63c0'	System	29 Sep 2020 23:29:16
User entered '29 Sep 2020 18:29'	System	29 Sep 2020 23:29:16

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 5'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 6'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '15366daa-ee97-40f0-9ce1-38f49b5ff419'	System	01 Oct 2020 23:27:48
User entered 'Yes (Y)'	System	01 Oct 2020 23:27:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '15366daa-ee97-40f0-9ce1-38f49b5ff419'	System	01 Oct 2020 23:27:48
User entered '97.5'	System	01 Oct 2020 23:27:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '15366daa-ee97-40f0-9ce1-38f49b5ff419'	System	01 Oct 2020 23:27:48
User entered 'No (N)'	System	01 Oct 2020 23:27:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '15366daa-ee97-40f0-9ce1-38f49b5ff419'	System	01 Oct 2020 23:27:48
User entered '01 Oct 2020 18:27'	System	01 Oct 2020 23:27:48

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 7'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ed317fdf-c2bf-41cd-b545-b7ea4a2fea77'	System	02 Oct 2020 21:47:21
User entered 'Yes (Y)'	System	02 Oct 2020 21:47:21

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:13', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ed317fdf-c2bf-41cd-b545-b7ea4a2fea77'	System	02 Oct 2020 21:47:21
User entered '97.7'	System	02 Oct 2020 21:47:21

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:16', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ed317fdf-c2bf-41cd-b545-b7ea4a2fea77'	System	02 Oct 2020 21:47:21
User entered 'No (N)'	System	02 Oct 2020 21:47:21

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ed317fdf-c2bf-41cd-b545-b7ea4a2fea77'	System	02 Oct 2020 21:47:21
User entered '02 Oct 2020 16:47'	System	02 Oct 2020 21:47:21

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:03', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '87a06a90-9405-4ebe-839d-1cb2621e09f0'	System	26 Sep 2020 18:50:31
User entered 'None (1)'	System	26 Sep 2020 18:50:31

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '87a06a90-9405-4ebe-839d-1cb2621e09f0'	System	26 Sep 2020 18:50:31
User entered 'No (N)'	System	26 Sep 2020 18:50:31

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '87a06a90-9405-4ebe-839d-1cb2621e09f0'	System	26 Sep 2020 18:50:31
User entered 'No (N)'	System	26 Sep 2020 18:50:31

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '87a06a90-9405-4ebe-839d-1cb2621e09f0'	System	26 Sep 2020 18:50:31
User entered 'None (1)'	System	26 Sep 2020 18:50:31

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:50:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '87a06a90-9405-4ebe-839d-1cb2621e09f0'	System	26 Sep 2020 18:50:31
User entered '26 Sep 2020 13:50'	System	26 Sep 2020 18:50:31

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 13:39'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 16:09'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '48e099a0-8aea-46b0-a03a-bdf7b473bd21'	System	27 Sep 2020 00:46:08
User entered 'None (1)'	System	27 Sep 2020 00:46:08

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:53', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '48e099a0-8aea-46b0-a03a-bdf7b473bd21'	System	27 Sep 2020 00:46:08
User entered 'No (N)'	System	27 Sep 2020 00:46:08

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:45:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '48e099a0-8aea-46b0-a03a-bdf7b473bd21'	System	27 Sep 2020 00:46:08
User entered 'No (N)'	System	27 Sep 2020 00:46:08

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '48e099a0-8aea-46b0-a03a-bdf7b473bd21'	System	27 Sep 2020 00:46:08
User entered 'None (1)'	System	27 Sep 2020 00:46:08

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:06', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '48e099a0-8aea-46b0-a03a-bdf7b473bd21'	System	27 Sep 2020 00:46:08
User entered '26 Sep 2020 19:46'	System	27 Sep 2020 00:46:08

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 17:04'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 2'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '59b1969e-bb02-4c21-a348-9c0501043f00'	System	28 Sep 2020 00:30:24
User entered 'None (1)'	System	28 Sep 2020 00:30:24

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '59b1969e-bb02-4c21-a348-9c0501043f00'	System	28 Sep 2020 00:30:24
User entered 'No (N)'	System	28 Sep 2020 00:30:24

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:08', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '59b1969e-bb02-4c21-a348-9c0501043f00'	System	28 Sep 2020 00:30:24
User entered 'No (N)'	System	28 Sep 2020 00:30:24

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '59b1969e-bb02-4c21-a348-9c0501043f00'	System	28 Sep 2020 00:30:24
User entered 'None (1)'	System	28 Sep 2020 00:30:24

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:22', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '59b1969e-bb02-4c21-a348-9c0501043f00'	System	28 Sep 2020 00:30:24
User entered '27 Sep 2020 19:30'	System	28 Sep 2020 00:30:24

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 3'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '17dfe58f-44ef-42f5-8177-19a99b43be3b'	System	28 Sep 2020 22:27:23
User entered 'None (1)'	System	28 Sep 2020 22:27:23

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '17dfe58f-44ef-42f5-8177-19a99b43be3b'	System	28 Sep 2020 22:27:23
User entered 'No (N)'	System	28 Sep 2020 22:27:23

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:14', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '17dfe58f-44ef-42f5-8177-19a99b43be3b'	System	28 Sep 2020 22:27:23
User entered 'No (N)'	System	28 Sep 2020 22:27:23

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '17dfe58f-44ef-42f5-8177-19a99b43be3b'	System	28 Sep 2020 22:27:23
User entered 'None (1)'	System	28 Sep 2020 22:27:23

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '17dfe58f-44ef-42f5-8177-19a99b43be3b'	System	28 Sep 2020 22:27:23
User entered '28 Sep 2020 17:27'	System	28 Sep 2020 22:27:23

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 4'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:22', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '81090a50-b39c-4607-9503-3d6f7c35bcff'	System	29 Sep 2020 23:29:53
User entered 'None (1)'	System	29 Sep 2020 23:29:53

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:34', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '81090a50-b39c-4607-9503-3d6f7c35bcff'	System	29 Sep 2020 23:29:53
User entered 'No (N)'	System	29 Sep 2020 23:29:53

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '81090a50-b39c-4607-9503-3d6f7c35bcff'	System	29 Sep 2020 23:29:53
User entered 'No (N)'	System	29 Sep 2020 23:29:53

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '81090a50-b39c-4607-9503-3d6f7c35bcff'	System	29 Sep 2020 23:29:53
User entered 'None (1)'	System	29 Sep 2020 23:29:53

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:29:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '81090a50-b39c-4607-9503-3d6f7c35bcff'	System	29 Sep 2020 23:29:53
User entered '29 Sep 2020 18:29'	System	29 Sep 2020 23:29:53

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 5'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 6'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dfff709-5c3a-4f3a-a405-3c1f24d60cfe'	System	01 Oct 2020 23:28:34
User entered 'None (1)'	System	01 Oct 2020 23:28:34

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dfff709-5c3a-4f3a-a405-3c1f24d60cfe'	System	01 Oct 2020 23:28:34
User entered 'No (N)'	System	01 Oct 2020 23:28:34

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:27:59', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dfff709-5c3a-4f3a-a405-3c1f24d60cfe'	System	01 Oct 2020 23:28:34
User entered 'No (N)'	System	01 Oct 2020 23:28:34

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dfff709-5c3a-4f3a-a405-3c1f24d60cfe'	System	01 Oct 2020 23:28:34
User entered 'None (1)'	System	01 Oct 2020 23:28:34

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:30', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dfff709-5c3a-4f3a-a405-3c1f24d60cfe'	System	01 Oct 2020 23:28:34
User entered '01 Oct 2020 18:28'	System	01 Oct 2020 23:28:34

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 7'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '80ebba2a-692a-4139-9037-aea34bc3cdd6'	System	02 Oct 2020 21:47:44
User entered 'None (1)'	System	02 Oct 2020 21:47:44

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '80ebba2a-692a-4139-9037-aea34bc3cdd6'	System	02 Oct 2020 21:47:44
User entered 'No (N)'	System	02 Oct 2020 21:47:44

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '80ebba2a-692a-4139-9037-aea34bc3cdd6'	System	02 Oct 2020 21:47:44
User entered 'No (N)'	System	02 Oct 2020 21:47:44

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '80ebba2a-692a-4139-9037-aea34bc3cdd6'	System	02 Oct 2020 21:47:44
User entered 'None (1)'	System	02 Oct 2020 21:47:44

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '80ebba2a-692a-4139-9037-aea34bc3cdd6'	System	02 Oct 2020 21:47:44
User entered '02 Oct 2020 16:47'	System	02 Oct 2020 21:47:44

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'None (0)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:48', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered 'No (N)'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T13:49:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '4038d48e-cb78-4c63-924d-c6ad28ffc5e1'	System	26 Sep 2020 18:49:54
User entered '26 Sep 2020 13:49'	System	26 Sep 2020 18:49:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 13:39'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 16:09'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:30', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'None (0)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '1dba9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered 'No (N)'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-26T19:46:58', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ldb9718-1e20-4408-a926-dfc1151e8884'	System	27 Sep 2020 00:47:03
User entered '26 Sep 2020 19:46'	System	27 Sep 2020 00:47:03

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '26 Sep 2020 17:04'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 2'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:29', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:33', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'None (0)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered 'No (N)'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-27T19:30:50', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'ff553da2-dd6d-4120-ad0a-9ad47e08836b'	System	28 Sep 2020 00:30:54
User entered '27 Sep 2020 19:30'	System	28 Sep 2020 00:30:54

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 3'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'None (0)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'None (0)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'None (0)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'None (0)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:48', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'None (0)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered 'No (N)'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-28T17:27:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '57b7cf9e-5eb7-458a-b794-f2856511c6dd'	System	28 Sep 2020 22:27:58
User entered '28 Sep 2020 17:27'	System	28 Sep 2020 22:27:58

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 4'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'None (0)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'None (0)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'Some interference with activity (2)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'Some interference with activity (2)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'None (0)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'None (0)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered 'No (N)'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-09-29T18:30:54', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '01234623-88d4-43c6-a9fb-c98fce71ba9d'	System	29 Sep 2020 23:30:59
User entered '29 Sep 2020 18:30'	System	29 Sep 2020 23:30:59

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 5'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 6'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:35', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'None (0)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered 'No (N)'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-01T18:28:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '27d8ed50-d07c-449c-9bd0-a3f60c090020'	System	01 Oct 2020 23:28:56
User entered '01 Oct 2020 18:28'	System	01 Oct 2020 23:28:56

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	26 Sep 2020 18:19:42
User entered 'Day 7'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:50', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:53', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:47:58', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:48:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'None (0)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:48:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered 'No (N)'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-02T16:48:05', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'da669cbb-c7c7-4209-97a6-2b3b05454387'	System	02 Oct 2020 21:48:07
User entered '02 Oct 2020 16:48'	System	02 Oct 2020 21:48:07

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 18:19:42

US3252382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 18:19:42

US3252382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Oct 2020 02:34:34
	(b) (4)	

US3252382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '3 Oct 2020'	Nancy Torrence (b) (4)	05 Oct 2020 02:34:34
	(b) (4)	

US3252382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	05 Oct 2020 02:34:34
	(b) (4)	

US3252382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	05 Oct 2020 02:34:34
	(b) (4)	

US3252382

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Oct 2020 02:34:38
	(b) (4)	

US3252382

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	05 Oct 2020 02:34:38

US3252382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 02:50:42
	(b) (4)	

US3252382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12 Oct 2020'	Nancy Torrence (b) (4)	13 Oct 2020 02:50:42
	(b) (4)	

US3252382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	13 Oct 2020 02:50:42
	(b) (4)	

US3252382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 02:50:42
	(b) (4)	

US3252382

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 02:50:46
	(b) (4)	

US3252382

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	13 Oct 2020 02:50:46

US3252382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	19 Oct 2020 02:35:07
	(b) (4)	

US3252382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '17 Oct 2020'	Nancy Torrence (b) (4)	19 Oct 2020 02:35:07
	(b) (4)	

US3252382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	19 Oct 2020 02:35:07
	(b) (4)	

US3252382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Nancy Torrence (b) (4)	19 Oct 2020 02:35:07
	(b) (4)	

US3252382

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	19 Oct 2020 02:35:11
	(b) (4)	

US3252382

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	19 Oct 2020 02:35:11

US3252382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:05
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '24 Oct 2020'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:05
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:05
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'VISIT3'	System	26 Oct 2020 02:56:05

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '24 Oct 2020'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:05'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '24 Oct 2020 12:05'	System	26 Oct 2020 02:56:56

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '98.0' F reason for change: Data Entry	(b) (4), (b) (6)	27 Oct 2020 16:09:10
Error		
User entered '98' F	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '92'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'bpm'	System	26 Oct 2020 02:56:56

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '16'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'breaths/min'	System	26 Oct 2020 02:56:56

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '116'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	26 Oct 2020 02:56:56

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '78'	Shannon Moyer (b) (4)	26 Oct 2020 02:56:56
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'mmHg'	System	26 Oct 2020 02:56:56

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26

US3252382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26

US3252382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'No (N)'	Shannon Moyer (b) (4)	26 Oct 2020 02:57:32
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered empty.	Shannon Moyer (b) (4)	26 Oct 2020 02:57:32
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Oct 2020 02:58:02
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '24 Oct 2020'	Shannon Moyer (b) (4)	26 Oct 2020 02:58:02
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered '12:16'	Shannon Moyer (b) (4)	26 Oct 2020 02:58:02
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered '24 Oct 2020 12:16'	System	26 Oct 2020 02:58:02

US3252382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:10:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Oct 2020 02:58:08
	(b) (4)	

US3252382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	26 Oct 2020 02:58:08

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 64'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-29T22:12:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '69afb5ac-1782-484c-a24f-a6cea7bc46b2'	System	30 Oct 2020 03:12:44
User entered 'No (N)'	System	30 Oct 2020 03:12:44

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-29T22:12:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '69afb5ac-1782-484c-a24f-a6cea7bc46b2'	System	30 Oct 2020 03:12:44
User entered 'No (N)'	System	30 Oct 2020 03:12:44

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-10-29T22:12:40', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '69afb5ac-1782-484c-a24f-a6cea7bc46b2'	System	30 Oct 2020 03:12:44
User entered '29 Oct 2020 22:12:40'	System	30 Oct 2020 03:12:44

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 71'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-05T09:21:30', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1257268-7199-4532-9bfa-04b7c53aa763'	System	05 Nov 2020 15:23:10
User entered 'No (N)'	System	05 Nov 2020 15:23:10

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-05T09:23:00', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1257268-7199-4532-9bfa-04b7c53aa763'	System	05 Nov 2020 15:23:10
User entered 'No (N)'	System	05 Nov 2020 15:23:10

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-05T09:23:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1257268-7199-4532-9bfa-04b7c53aa763'	System	05 Nov 2020 15:23:10
User entered '05 Nov 2020 09:23:04'	System	05 Nov 2020 15:23:10

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered 'Day 78'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-12T18:23:10', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fa2eb481-8a1c-4afd-a063-331e6ad644a4'	System	13 Nov 2020 00:23:23
User entered 'No (N)'	System	13 Nov 2020 00:23:23

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-12T18:23:16', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fa2eb481-8a1c-4afd-a063-331eead644a4'	System	13 Nov 2020 00:23:23
User entered 'No (N)'	System	13 Nov 2020 00:23:23

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-12T18:23:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fa2eb481-8a1c-4afd-a063-331eead644a4'	System	13 Nov 2020 00:23:23
User entered '12 Nov 2020 18:23:20'	System	13 Nov 2020 00:23:23

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 16:41:45

US3252382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:01:51
Data entry locked.	System	29 Aug 2020 16:41:45
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 16:41:45

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-11-20T08:13:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b9234894-11a1-4653-9896-418d6bbb793a'	System	20 Nov 2020 14:13:25
User entered 'No (N)'	System	20 Nov 2020 14:13:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-11-20T08:13:14', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b9234894-11a1-4653-9896-418d6bbb793a'	System	20 Nov 2020 14:13:25
User entered 'No (N)'	System	20 Nov 2020 14:13:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-20T08:13:22', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b9234894-11a1-4653-9896-418d6bbb793a'	System	20 Nov 2020 14:13:25
User entered '20 Nov 2020 08:13:22'	System	20 Nov 2020 14:13:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-11-25T12:04:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8e7c00b3-8b98-43f2-90fb-b526d829703c'	System	25 Nov 2020 18:04:42
User entered 'No (N)'	System	25 Nov 2020 18:04:42

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-11-25T12:04:29', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8e7c00b3-8b98-43f2-90fb-b526d829703c'	System	25 Nov 2020 18:04:42
User entered 'No (N)'	System	25 Nov 2020 18:04:42

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-25T12:04:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8e7c00b3-8b98-43f2-90fb-b526d829703c'	System	25 Nov 2020 18:04:42
User entered '25 Nov 2020 12:04:38'	System	25 Nov 2020 18:04:42

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-11-30T20:08:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b4962583-2c8b-4d62-ba9e-f68281970dc2'	System	01 Dec 2020 02:08:15
User entered 'No (N)'	System	01 Dec 2020 02:08:15

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-11-30T20:08:08', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b4962583-2c8b-4d62-ba9e-f68281970dc2'	System	01 Dec 2020 02:08:15
User entered 'No (N)'	System	01 Dec 2020 02:08:15

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-11-30T20:08:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b4962583-2c8b-4d62-ba9e-f68281970dc2'	System	01 Dec 2020 02:08:15
User entered '30 Nov 2020 20:08:12'	System	01 Dec 2020 02:08:15

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-12-07T16:17:11', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c9369297-1ae0-4fc0-9d4e-80c1afb0aaf7'	System	07 Dec 2020 22:17:27
User entered 'No (N)'	System	07 Dec 2020 22:17:27

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-12-07T16:17:18', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c9369297-1ae0-4fc0-9d4e-80c1afb0aaf7'	System	07 Dec 2020 22:17:27
User entered 'No (N)'	System	07 Dec 2020 22:17:27

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-12-07T16:17:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c9369297-1ae0-4fc0-9d4e-80c1afb0aaf7'	System	07 Dec 2020 22:17:27
User entered '07 Dec 2020 16:17:21'	System	07 Dec 2020 22:17:27

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-12-15T12:45:50', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '40c796e6-e578-41c5-a344-0edfecbc542f'	System	15 Dec 2020 18:46:08
User entered 'No (N)'	System	15 Dec 2020 18:46:08

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-12-15T12:45:55', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '40c796e6-e578-41c5-a344-0edfecbc542f'	System	15 Dec 2020 18:46:08
User entered 'No (N)'	System	15 Dec 2020 18:46:08

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-12-15T12:46:01', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '40c796e6-e578-41c5-a344-0edfecbc542f'	System	15 Dec 2020 18:46:08
User entered '15 Dec 2020 12:46:01'	System	15 Dec 2020 18:46:08

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-12-21T04:07:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c910673a-796c-4710-a7c4-be6f8807f901'	System	21 Dec 2020 10:07:59
User entered 'No (N)'	System	21 Dec 2020 10:07:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-12-21T04:07:52', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c910673a-796c-4710-a7c4-be6f8807f901'	System	21 Dec 2020 10:07:59
User entered 'No (N)'	System	21 Dec 2020 10:07:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-12-21T04:07:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'c910673a-796c-4710-a7c4-be6f8807f901' User entered '21 Dec 2020 04:07:56'	System	21 Dec 2020 10:07:59
	System	21 Dec 2020 10:07:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2020-12-28T00:43:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'cccb3c4e-0fc1-498c-9cc1-aa75a663c837'	System	28 Dec 2020 06:43:56
User entered 'No (N)'	System	28 Dec 2020 06:43:56

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2020-12-28T00:43:46', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'cccb3c4e-0fc1-498c-9cc1-aa75a663c837'	System	28 Dec 2020 06:43:56
User entered 'No (N)'	System	28 Dec 2020 06:43:56

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2020-12-28T00:43:53', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'cccb3c4e-0fc1-498c-9cc1-aa75a663c837'	System	28 Dec 2020 06:43:56
User entered '28 Dec 2020 00:43:53'	System	28 Dec 2020 06:43:56

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-01-04T00:22:11', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61a3930a-aeefa-42ed-a614-5970422e0ab9'	System	04 Jan 2021 06:22:25
User entered 'No (N)'	System	04 Jan 2021 06:22:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-01-04T00:22:16', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61a3930a-aefa-42ed-a614-5970422e0ab9'	System	04 Jan 2021 06:22:25
User entered 'No (N)'	System	04 Jan 2021 06:22:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-01-04T00:22:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '61a3930a-aefa-42ed-a614-5970422e0ab9' User entered '04 Jan 2021 00:22:20'	System	04 Jan 2021 06:22:25
	System	04 Jan 2021 06:22:25

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-01-11T09:39:22', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0dd83fc8-8cf3-4a31-a125-5266d84ab580'	System	11 Jan 2021 15:39:35
User entered 'No (N)'	System	11 Jan 2021 15:39:35

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-01-11T09:39:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0dd83fc8-8cf3-4a31-a125-5266d84ab580'	System	11 Jan 2021 15:39:35
User entered 'No (N)'	System	11 Jan 2021 15:39:35

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-01-11T09:39:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '0dd83fc8-8cf3-4a31-a125-5266d84ab580'	System	11 Jan 2021 15:39:35
User entered '11 Jan 2021 09:39:31'	System	11 Jan 2021 15:39:35

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-01-19T06:47:24', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1ab0c0b-2f0f-4725-ae8f-e5d6ab2f980f'	System	19 Jan 2021 12:47:36
User entered 'No (N)'	System	19 Jan 2021 12:47:36

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-01-19T06:47:31', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1ab0c0b-2f0f-4725-ae8f-e5d6ab2f980f'	System	19 Jan 2021 12:47:36
User entered 'No (N)'	System	19 Jan 2021 12:47:36

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-01-19T06:47:34', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'd1ab0c0b-2f0f-4725-ae8f-e5d6ab2f980f' User entered '19 Jan 2021 06:47:34'	System	19 Jan 2021 12:47:36

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-01-27T06:41:59', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '985c23f1-2711-47d2-9227-389e5de04bcc'	System	27 Jan 2021 12:42:13
User entered 'No (N)'	System	27 Jan 2021 12:42:13

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-01-27T06:42:06', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '985c23f1-2711-47d2-9227-389e5de04bcc'	System	27 Jan 2021 12:42:13
User entered 'No (N)'	System	27 Jan 2021 12:42:13

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-01-27T06:42:09', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '985c23f1-2711-47d2-9227-389e5de04bcc'	System	27 Jan 2021 12:42:13
User entered '27 Jan 2021 06:42:09'	System	27 Jan 2021 12:42:13

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-02-01T12:35:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fbc95f47-3a6a-4a58-95f8-e062882589d3'	System	01 Feb 2021 18:35:23
User entered 'No (N)'	System	01 Feb 2021 18:35:23

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-02-01T12:35:17', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fbc95f47-3a6a-4a58-95f8-e062882589d3'	System	01 Feb 2021 18:35:23
User entered 'No (N)'	System	01 Feb 2021 18:35:23

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-02-01T12:35:19', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'fbc95f47-3a6a-4a58-95f8-e062882589d3'	System	01 Feb 2021 18:35:23
User entered '01 Feb 2021 12:35:19'	System	01 Feb 2021 18:35:23

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-02-08T00:20:53', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f17ef450-e162-41a9-a028-4b04df2d2c46'	System	08 Feb 2021 06:21:09
User entered 'No (N)'	System	08 Feb 2021 06:21:09

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-02-08T00:21:01', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f17ef450-e162-41a9-a028-4b04df2d2c46'	System	08 Feb 2021 06:21:09
User entered 'No (N)'	System	08 Feb 2021 06:21:09

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-02-08T00:21:05', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f17ef450-e162-41a9-a028-4b04df2d2c46'	System	08 Feb 2021 06:21:09
User entered '08 Feb 2021 00:21:05'	System	08 Feb 2021 06:21:09

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-02-15T17:55:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b3f4148e-5966-4623-adfe-b307e0f90a69'	System	15 Feb 2021 23:55:46
User entered 'No (N)'	System	15 Feb 2021 23:55:46

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-02-15T17:55:38', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b3f4148e-5966-4623-adfe-b307e0f90a69'	System	15 Feb 2021 23:55:46
User entered 'No (N)'	System	15 Feb 2021 23:55:46

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-02-15T17:55:41', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'b3f4148e-5966-4623-adfe-b307e0f90a69'	System	15 Feb 2021 23:55:46
User entered '15 Feb 2021 17:55:41'	System	15 Feb 2021 23:55:46

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-02-24T15:04:44', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f5391e12-e857-4601-8681-0330dcb43d6e'	System	24 Feb 2021 21:04:57
User entered 'No (N)'	System	24 Feb 2021 21:04:57

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-02-24T15:04:51', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f5391e12-e857-4601-8681-0330dcb43d6e'	System	24 Feb 2021 21:04:57
User entered 'No (N)'	System	24 Feb 2021 21:04:57

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-02-24T15:04:54', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'f5391e12-e857-4601-8681-0330dcb43d6e' User entered '24 Feb 2021 15:04:54'	System	24 Feb 2021 21:04:57
	System	24 Feb 2021 21:04:57

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-03-01T06:44:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dafbed68-ff44-4b43-b8fd-957b2eab0a3a'	System	01 Mar 2021 12:44:40
User entered 'No (N)'	System	01 Mar 2021 12:44:40

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-03-01T06:44:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dafbed68-ff44-4b43-b8fd-957b2eab0a3a'	System	01 Mar 2021 12:44:40
User entered 'No (N)'	System	01 Mar 2021 12:44:40

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-01T06:44:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'dafbed68-ff44-4b43-b8fd-957b2eab0a3a'	System	01 Mar 2021 12:44:40
User entered '01 Mar 2021 06:44:36'	System	01 Mar 2021 12:44:40

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-03-08T06:25:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8499f5c2-11e8-4eee-b636-7dc6af3f9d85'	System	08 Mar 2021 12:25:38
User entered 'No (N)'	System	08 Mar 2021 12:25:38

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-03-08T06:25:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8499f5c2-11e8-4eee-b636-7dc6af3f9d85'	System	08 Mar 2021 12:25:38
User entered 'No (N)'	System	08 Mar 2021 12:25:38

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-08T06:25:33', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '8499f5c2-11e8-4eee-b636-7dc6af3f9d85'	System	08 Mar 2021 12:25:38
User entered '08 Mar 2021 06:25:33'	System	08 Mar 2021 12:25:38

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-03-15T06:59:59', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '9df3d0eb-cf9b-4b29-ad28-263923f1361c'	System	15 Mar 2021 12:00:14
User entered 'No (N)'	System	15 Mar 2021 12:00:14

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-03-15T07:00:07', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '9df3d0eb-cf9b-4b29-ad28-263923f1361c'	System	15 Mar 2021 12:00:14
User entered 'No (N)'	System	15 Mar 2021 12:00:14

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-15T07:00:10', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '9df3d0eb-cf9b-4b29-ad28-263923f1361c'	System	15 Mar 2021 12:00:14
User entered '15 Mar 2021 07:00:10'	System	15 Mar 2021 12:00:14

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-03-22T09:57:28', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '10ed591b-90fd-4310-b9ef-c7ff7bb0c0a5'	System	22 Mar 2021 14:57:52
User entered 'No (N)'	System	22 Mar 2021 14:57:52

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-03-22T09:57:42', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '10ed591b-90fd-4310-b9ef-c7ff7bb0c0a5'	System	22 Mar 2021 14:57:52
User entered 'No (N)'	System	22 Mar 2021 14:57:52

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-22T09:57:47', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '10ed591b-90fd-4310-b9ef-c7ff7bb0c0a5'	System	22 Mar 2021 14:57:52
User entered '22 Mar 2021 09:57:47'	System	22 Mar 2021 14:57:52

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-03-29T20:51:58', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a1ba3ea8-93b4-4a0b-a514-0f04a4cc34d5'	System	30 Mar 2021 01:52:12
User entered 'No (N)'	System	30 Mar 2021 01:52:12

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-03-29T20:52:02', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a1ba3ea8-93b4-4a0b-a514-0f04a4cc34d5'	System	30 Mar 2021 01:52:12
User entered 'No (N)'	System	30 Mar 2021 01:52:12

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-29T20:52:06', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'a1ba3ea8-93b4-4a0b-a514-0f04a4cc34d5'	System	30 Mar 2021 01:52:12
User entered '29 Mar 2021 20:52:06'	System	30 Mar 2021 01:52:12

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-05T07:33:14', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'def9c1b1-f012-4483-90c9-5e0472362a78'	System	05 Apr 2021 12:33:30
User entered 'No (N)'	System	05 Apr 2021 12:33:30

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-04-05T07:33:23', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'def9c1b1-f012-4483-90c9-5e0472362a78'	System	05 Apr 2021 12:33:30
User entered 'No (N)'	System	05 Apr 2021 12:33:30

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-04-05T07:33:26', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'def9c1b1-f012-4483-90c9-5e0472362a78'	System	05 Apr 2021 12:33:30
User entered '05 Apr 2021 07:33:26'	System	05 Apr 2021 12:33:30

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-12T10:44:45', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '35a81103-473f-4cce-a0c3-b9581a915e52'	System	12 Apr 2021 15:44:59
User entered 'No (N)'	System	12 Apr 2021 15:44:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-04-12T10:44:49', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '35a81103-473f-4cce-a0c3-b9581a915e52'	System	12 Apr 2021 15:44:59
User entered 'No (N)'	System	12 Apr 2021 15:44:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-04-12T10:44:54', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '35a81103-473f-4cce-a0c3-b9581a915e52'	System	12 Apr 2021 15:44:59
User entered '12 Apr 2021 10:44:54'	System	12 Apr 2021 15:44:59

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-19T03:38:48', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e93d3183-83c3-47be-a561-5814140433e7'	System	19 Apr 2021 08:39:48
User entered 'Yes (Y)'	System	19 Apr 2021 08:39:48

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-04-19T03:38:56', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e93d3183-83c3-47be-a561-5814140433e7'	System	19 Apr 2021 08:39:48
User entered 'No (N)'	System	19 Apr 2021 08:39:48

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-19T03:39:04', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e93d3183-83c3-47be-a561-5814140433e7'	System	19 Apr 2021 08:39:48
User entered 'No (N)'	System	19 Apr 2021 08:39:48

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-19T03:39:39', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e93d3183-83c3-47be-a561-5814140433e7'	System	19 Apr 2021 08:39:48
User entered 'No (N)'	System	19 Apr 2021 08:39:48

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-04-19T03:39:43', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'e93d3183-83c3-47be-a561-5814140433e7'	System	19 Apr 2021 08:39:48
User entered '19 Apr 2021 03:39:43'	System	19 Apr 2021 08:39:48

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-04-26T00:20:15', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '2bd18f13-ddce-49c1-bbcc-2fa01d726819'	System	26 Apr 2021 05:20:28
User entered 'No (N)'	System	26 Apr 2021 05:20:28

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-04-26T00:20:21', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '2bd18f13-ddce-49c1-bbcc-2fa01d726819'	System	26 Apr 2021 05:20:28
User entered 'No (N)'	System	26 Apr 2021 05:20:28

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-04-26T00:20:25', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '2bd18f13-ddce-49c1-bbcc-2fa01d726819'	System	26 Apr 2021 05:20:28
User entered '26 Apr 2021 00:20:25'	System	26 Apr 2021 05:20:28

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[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 (9a969c2a2f47aafd)', Time: '2021-05-03T06:21:27', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '36967427-b291-4335-adf9-62b364093325'	System	03 May 2021 11:21:41
User entered 'No (N)'	System	03 May 2021 11:21:41

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Have you been exposed to someone with 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 (9a969c2a2f47aafd)', Time: '2021-05-03T06:21:32', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '36967427-b291-4335-adf9-62b364093325'	System	03 May 2021 11:21:41
User entered 'No (N)'	System	03 May 2021 11:21:41

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-05-03T06:21:36', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: '36967427-b291-4335-adf9-62b364093325'	System	03 May 2021 11:21:41
User entered '03 May 2021 06:21:36'	System	03 May 2021 11:21:41

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:31:22

US3252382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:22
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:31:22

US3252382

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:13:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-01T06:45:12', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'de12d2cb-5c03-4b00-8f45-da62f0c9e836'	System	01 Mar 2021 12:45:23
User entered 'No (N)'	System	01 Mar 2021 12:45:23

US3252382

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:13:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a969c2a2f47aafd)', Time: '2021-03-01T06:45:20', User OID: 'PatientReportedOutcome (US3252382)', ODM File OID: 'de12d2cb-5c03-4b00-8f45-da62f0c9e836'	System	01 Mar 2021 12:45:23
User entered '01 Mar 2021 06:45:20'	System	01 Mar 2021 12:45:23

US3252382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Nov 2020 03:20:17
	(b) (4)	

US3252382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '23 Nov 2020'	Shannon Moyer (b) (4)	24 Nov 2020 03:20:17
	(b) (4)	

US3252382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	24 Nov 2020 03:20:17
	(b) (4)	

US3252382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	24 Nov 2020 03:20:17
	(b) (4)	

US3252382

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Nov 2020 03:20:21
	(b) (4)	

US3252382

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:54:26
User entered 'I'	System	24 Nov 2020 03:20:21

US3252382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:32

US3252382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '15 Dec 2020'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:32

US3252382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:32

US3252382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'LEFT VOICE MESSAGE.'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:32

US3252382

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:37

US3252382

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered 'I'	System	06 Feb 2021 02:47:37

US3252382

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:51

US3252382

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 15:15:28
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'PER SOURCE CORRECT AS IT IS.' (Site from System).	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:48:16
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Feb 2021 02:47:51
User entered '2 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:51

US3252382

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:51

US3252382

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:47:51

US3252382

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	06 Feb 2021 02:48:23

US3252382

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered 'I'	System	06 Feb 2021 02:48:23

US3252382

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 02:54:22

US3252382

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 02:54:22

US3252382

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Feb 2021 02:54:22

US3252382

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 02:54:22

US3252382

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 02:54:27

US3252382

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered 'I'	System	24 Feb 2021 02:54:27

US3252382

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 02:37:07

US3252382

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 02:37:07

US3252382

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Mar 2021 02:37:07

US3252382

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered 'VISIT4'	System	25 Mar 2021 02:37:07

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered empty.	System	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered empty.	System	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered empty.	System	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered empty.	System	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered empty.	System	30 Mar 2021 19:13:52

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16

US3252382

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:13:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16

US3252382

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 02:41:41

US3252382

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 02:41:41

US3252382

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 02:42:19

US3252382

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 02:42:19

US3252382

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '13:21'	(b) (4), (b) (6)	25 Mar 2021 02:42:19

US3252382

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered '24 Mar 2021 13:21'	System	25 Mar 2021 02:42:19

US3252382

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 02:42:29

US3252382

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:16
User entered 'I'	System	25 Mar 2021 02:42:29

US3252382

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 02:22:17

US3252382

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
User entered '23 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 02:22:17

US3252382

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Apr 2021 02:22:17

US3252382

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 02:22:17

US3252382

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 02:22:08

US3252382

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 02:22:08

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:57:41

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:57:41

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[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 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Mar 2021 04:57:41

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'UNBLND_DECIDE'	System	10 Mar 2021 04:57:41

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1'	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:13:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '1'	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	10 Mar 2021 04:59:27
DataPoint set to visible.	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	10 Mar 2021 04:59:27
DataPoint set to visible.	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '13:24'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '9 Mar 2021 13:24'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '98.0' F	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '97'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'bpm'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '15'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'breaths/min'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '112'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '75'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:13:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered empty.	System	10 Mar 2021 04:59:27
DataPoint set to visible.	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '14:35'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '9 Mar 2021 14:35'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '97.9' F	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '88'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'bpm'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '15'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'breaths/min'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '131'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '86'	(b) (4), (b) (6)	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mmHg'	System	10 Mar 2021 04:59:27

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 04:59:33

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:59:33

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

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 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'mRNA-1273'	System	10 Mar 2021 04:59:59
DataPoint set to visible.	System	10 Mar 2021 04:58:04

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '13:52'	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '9 Mar 2021 13:52'	System	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.		23 Apr 2021 17:15:07
User closed query 'Source states right arm. Please review and update accordingly. ' (Site from CRA).		23 Apr 2021 17:15:05
Query 'Source states right arm. Please review and update accordingly. ' answered with 'UPDATED' (Site from CRA).		07 Apr 2021 03:16:31
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 03:16:23
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error		07 Apr 2021 03:16:23
DataPoint Un-verified.		06 Apr 2021 20:33:35
DataPoint Verified.		06 Apr 2021 20:33:33
User opened query 'Source states right arm. Please review and update accordingly. ' (Site from CRA).		06 Apr 2021 20:33:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:33:33
User entered 'ONCE'	System	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 04:59:59

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:00:19

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 05:00:19

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '13:44'	(b) (4), (b) (6)	10 Mar 2021 05:00:19

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '9 Mar 2021 13:44'	System	10 Mar 2021 05:00:19

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:00:29

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 05:00:29

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:13:17

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '13:44'	(b) (4), (b) (6)	10 Mar 2021 05:00:29

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:13:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered '9 Mar 2021 13:44'	System	10 Mar 2021 05:00:29

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:00:34

US3252382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:15:09
User entered 'I'	System	10 Mar 2021 05:00:34

US3252382

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 03:23:27

US3252382

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered '16 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 03:23:27

US3252382

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 03:23:27

US3252382

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 03:23:27

US3252382

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 03:23:33

US3252382

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User entered 'I'	System	17 Mar 2021 03:23:33

US3252382

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:31
User entered '1'	System	17 Mar 2021 03:23:33
DataPoint set to visible.	System	17 Mar 2021 03:23:33

US3252382

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:13:48

US3252382

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:13:48

US3252382

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Apr 2021 03:13:48

US3252382

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:13:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	07 Apr 2021 03:13:48

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '09:10'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 09:10'	System	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '97.8' F	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '86'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '16'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '117'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '80'	(b) (4), (b) (6)	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:14:25

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '10:00'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:00'	System	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '98.5' F	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '79'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '15'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '124'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '82'	(b) (4), (b) (6)	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 03:14:59

US3252382

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 03:15:07

US3252382

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:13:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:15:07

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	07 Apr 2021 03:15:34
DataPoint set to visible.	System	17 Mar 2021 03:23:33

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '6 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered '09:25'	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 09:25'	System	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	07 Apr 2021 03:16:23
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	07 Apr 2021 03:16:23
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	07 Apr 2021 03:15:34
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:13:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Apr 2021 03:15:34

US3252382

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 03:16:43

US3252382

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 03:16:43

US3252382

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:13:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:51:23
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:48:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:48:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	10 Sep 2020 23:41:27
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:38:59

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:53:58
User entered 'USA-US108-2021-mRNA-1273-P301000019'	System	16 Apr 2021 18:48:50
User entered 'New'	(b) (4), (b) (6)	16 Apr 2021 18:48:50

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 21:54:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Apr 2021 21:54:00
Data point term sent to Coder	System	15 Apr 2021 21:53:07
User entered 'Atypical chest pain'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Apr 2021'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[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	15 Apr 2021 21:53:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:53:49
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	15 Apr 2021 21:52:08
User entered '21:40'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:53:49
User entered '13 Apr 2021 21:40'	System	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:53:49
User entered '15 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:53:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:52:08
User entered '15 2021' (non-conformant).	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[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	15 Apr 2021 21:53:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:53:49
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	15 Apr 2021 21:52:08
User entered '15:35'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:53:49
User entered '15 2021 15:35' (non-conformant).	System	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[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)	16 Apr 2021 14:00:33
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 dates ' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 21:54:01
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	15 Apr 2021 21:52:08
User entered '1'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:53:49
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:53:49
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'still pending medical records subject was not discharged with any medication. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:55:58
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)	22 Apr 2021 12:33:08
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if any other relevant diagnostic tests were performed (ex: ECG, chest x-ray, etc.). If not, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:33:15
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)	22 Apr 2021 12:32:43
User opened query 'PV Query: Please provide date of stress test and troponins. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:32:34
User entered 'On Day 36 safety call subject reported being hospitalized for the past two days. Subject started with substernal chest pain around 21:00 on the 13th of APR 2021. The subject was evaluated at a local free standing emergency department that night. Subject was admitted for observation with a diagnosis of atypical chest pain, negative troponins, cardiology recommended a stress test, that the patient underwent showing no reversible ischemic changes, the subject was discharged home in stable condition with arrangement for outpatient follow-up today the 15th of APR 2021'	(b) (4), (b) (6)	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 21:52:08

US3252382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:13:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 21:52:08

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:13:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:51:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:09
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 21:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 21:06:43
Data point term sent to Coder	System	18 Sep 2020 15:46:25
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:46:22
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 02:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 02:12:42
Data point term sent to Coder	System	31 Aug 2020 21:40:31
User entered 'Anastrozole'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:26:49
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'Indication of medication is tied to underlying medical condition of breast cancer.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:46:53
User entered 'Estrogen control for breast cancer' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:46:22
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 01:45:13
User entered 'hormonal control'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:39:55

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '1'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'mg (mg)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN UNK 2016'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:39:55
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:39:55

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:39:55

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:39:55

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:43:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:43:47
Data point term sent to Coder	System	31 Aug 2020 21:41:32
User entered 'Venlafaxine'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:41:10

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:27:04
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Condition added to MH eCRF.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:37:20
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 02:30:41
User entered 'menopause'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:41:10

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '37.5'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'mg (mg)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN UNK 2016'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:41:10
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:41:10

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:41:10

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:41:10

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:45:53
Data point term sent to Coder Coding entries removed.	System Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:45:22 18 Sep 2020 15:44:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:43:36
Data point term sent to Coder User entered 'Prolia'	System Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:42:33 31 Aug 2020 21:42:29

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'osteoporosis'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '60'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'mg (mg)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'other (OTHER)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Twice a year'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:23:14
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Route updated appropriately.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:45:09
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:44:59
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 02:29:09
User entered 'Intramuscular (INTRAMUSCULAR)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN UNK 2016'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:42:29
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:42:29

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:42:29

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:42:29

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:44:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:44:38
Data point term sent to Coder	System	31 Aug 2020 21:43:36
User entered 'Calcium supplement'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'general health'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '1'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'capsule (CAPSULE)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN Mar 2016'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:43:22
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:43:22

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:43:22

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:43:22

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:45:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:45:41
Data point term sent to Coder	System	31 Aug 2020 21:44:37
User entered 'vitamin D'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'general health'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:46:47
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose and unit updated appropriately.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:41:24
User entered '600' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:41:04
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 05:46:26
User entered '1'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:44:02

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'TU (IU)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:41:04
User entered 'capsule (CAPSULE)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN May 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:02
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:44:02

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:44:02

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:44:02

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
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: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 11:58:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 11:58:53
Data point term sent to Coder	System	31 Aug 2020 21:45:38
User entered 'vitamin B1'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'general health'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:47:05
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dose and unit updated appropriately.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:27
User entered '100' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:16
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 05:48:14
User entered '1'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'mg (mg)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:16
User entered 'capsule (CAPSULE)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN May 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:44:51
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:44:51

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:44:51

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:44:51

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 21:46:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 21:46:36
Data point term sent to Coder	System	31 Aug 2020 21:45:38
User entered 'vitamin C'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'general health'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:47:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose and unit updated appropriately.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:57
User entered '75' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 05:47:40
User entered '1'	Shannon Moyer (b) (4) (b) (4)	31 Aug 2020 21:45:24

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'mg (mg)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	18 Sep 2020 15:43:46
User entered 'capsule (CAPSULE)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'UN May 2020'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered '0'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered empty.	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:24
	(b) (4)	

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:45:24

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:45:24

US3252382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:45:24

US3252382

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:13:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:36:56
User entered 'No (N)'	Shannon Moyer (b) (4)	31 Aug 2020 21:45:36
	(b) (4)	

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'USA-US108-2021-MRNA-1273-P301000019'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Yes (Y)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Yes (Y)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Joel'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Solis'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered '5201 N. 10th Street'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Mcallen'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'TX'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'carmpa'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
User entered 'US'	System	16 Apr 2021 19:13:48

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:13:48

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'USA-US108-2021-MRNA-1273-P301000019'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Yes (Y)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Yes (Y)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'No (N)'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Joel'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Solis'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered '5201 N. 10th Street'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'Mcallen'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'TX'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:57:20
User entered 'carmpa'	System	16 Apr 2021 18:48:50

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
User entered 'US'	System	16 Apr 2021 19:13:48

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:13:48

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
User entered '16/Apr/2021 12:13'	System	16 Apr 2021 19:13:48

US3252382

Folder: SAE USA-US108-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:13:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 19:13:48
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:58:25