

US3252215 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:11:44

All time stamps listed in this document are displayed in GMT

US3252215

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

[Participant ID](#)

US3252215

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

US3252215

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 01:17:39

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 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 checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 01:17:39

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 01:17:39

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Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Condition	HERNIA REPAIR
Start date (dd MMM yyyy)	UN JAN 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:04 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:04
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	170.4 lb
BMI (<i>xxx.x</i>)	28.41533 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:17:39

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 01:17:39

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 01:17:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186713

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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)	17 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:04
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)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 16:01
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 15:11 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 15:11

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

17 AUG 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	17 AUG 2020 14:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:07

PC Open Date & Time

17 AUG 2020 15:31

PC Close Date & Time

17 AUG 2020 18:01

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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 93.3 °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	17 AUG 2020 19:55
PC Open Date & Time	17 AUG 2020 18:56
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

97.3 °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

19 AUG 2020 12:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:11

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

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

22 AUG 2020 12:06

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

23 AUG 2020 13:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 16:08

PC Open Date & Time

17 AUG 2020 15:31

PC Close Date & Time

17 AUG 2020 18:01

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

17 AUG 2020 19:57

PC Open Date & Time

17 AUG 2020 18:56

PC Close Date & Time

18 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

18 AUG 2020 12:06

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

19 AUG 2020 12:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

20 AUG 2020 12:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

21 AUG 2020 12:12

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

22 AUG 2020 12:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

23 AUG 2020 13:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 16:08
PC Open Date & Time	17 AUG 2020 15:31
PC Close Date & Time	17 AUG 2020 18:01

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 19:48
PC Open Date & Time	17 AUG 2020 18:56
PC Close Date & Time	18 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:08
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

49 of 2031

EAB) (1725)

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:10
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

51 of 2031

EAB) (1725)

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

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)

55 of 2031

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:08
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3252215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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)	14 SEP 2020
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:11
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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)	14 SEP 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 09:25
Temperature (xxx.x)	97.8 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)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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.

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 08:47 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 08:47

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

US3252215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

14 SEP 2020 08:35

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:28	14 SEP 2020 08:28
Nasopharyngeal Swab 2	No		

US3252215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 09:35

PC Open Date & Time

14 SEP 2020 09:07

PC Close Date & Time

14 SEP 2020 11:37

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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 98.0 °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	14 SEP 2020 16:13
PC Open Date & Time	14 SEP 2020 12:32
PC Close Date & Time	15 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

98.3 °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

15 SEP 2020 13:23

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 15:54

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

18 SEP 2020 12:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

97.8 °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

19 SEP 2020 17:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

20 SEP 2020 12:58

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 09:36

PC Open Date & Time

14 SEP 2020 09:07

PC Close Date & Time

14 SEP 2020 11:37

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

14 SEP 2020 16:14

PC Open Date & Time

14 SEP 2020 12:32

PC Close Date & Time

15 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

15 SEP 2020 13:24

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

16 SEP 2020 12:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

17 SEP 2020 15:56

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

18 SEP 2020 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

19 SEP 2020 17:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

20 SEP 2020 12:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 09:37
PC Open Date & Time	14 SEP 2020 09:07
PC Close Date & Time	14 SEP 2020 11:37

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 16:16
PC Open Date & Time	14 SEP 2020 12:32
PC Close Date & Time	15 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 13:27
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:06
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

95 of 2031

EAB) (1725)

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 15:57
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

99 of 2031

EAB) (1725)

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 17:05
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

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 ☒

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3252215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:11 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:11
Temperature (<i>xxx.x</i>)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

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.

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:19 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:19

US3252215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:17:39

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 12:39:10
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

26 OCT 2020 09:45:58

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

02 NOV 2020 16:28:30

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 10:58:38

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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	19 NOV 2020 09:51:08
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

25 NOV 2020 08:02:32

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 DEC 2020 09:18:41
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

09 DEC 2020 09:07:45

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 DEC 2020 09:13:15
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

23 DEC 2020 09:10:31

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

31 DEC 2020 07:48:22

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

06 JAN 2021 09:53:35

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

13 JAN 2021 09:43:40

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

20 JAN 2021 13:58:44

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 08:15:42

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

03 FEB 2021 06:40:22

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

10 FEB 2021 20:29:24

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 07:47:57

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 10:00:27

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

06 MAR 2021 09:28:13

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

10 MAR 2021 07:30:12

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

17 MAR 2021 09:11:25

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

24 MAR 2021 10:28:10

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

31 MAR 2021 11:30:36

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 09:47:27

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

14 APR 2021 15:18:59

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

23 APR 2021 17:01:53

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Date and time of submission

28 APR 2021 09:49:58

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2021 00:01
Patient Cloud Close Date & Time	08 AUG 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Patient Cloud Open Date & Time	22 SEP 2021 00:01
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Patient Cloud Close Date & Time	26 SEP 2021 23:59
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US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 <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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3252215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:11:44

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 10:01:12

US3252215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 02:04:47

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments
If Contact Not Made, please provide Comments

PATIENT WAS CONTACTED
FOR SAFETY CALL BUT DID
NOT RETURN CALL, CALL WAS
THEREFORE MISSED.

US3252215

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 19:54:26

Generated On: 09 Jun 2021 16:11:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:45 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 07:45
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

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.

US3252215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3252215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252215

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:44

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"/>

US3252215

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:11:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252215

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 JAN 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

US3252215

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:54:26

Generated On: 09 Jun 2021 16:11:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	7 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	7 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3252215

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Height	141 cm
Weight	79.5 kg
BMI (xxx.x)	39.98793

US3252215

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Height	141 cm
Weight	79.5 kg
BMI (xxx.x)	39.98793
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)	7 JAN 2021
Time of assessment (00:00-23:59)	07:37 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 07:37
Temperature (xxx.x)	98.6 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Height	141 cm
Weight	79.5 kg
BMI (xxx.x)	39.98793
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)	7 JAN 2021
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 08:57
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 JAN 2021

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

US3252215

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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) 7 JAN 2021

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

Treatment Date and Time (derived) 7 JAN 2021 08:23

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

US3252215

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00-23:59)	08:04 (24 HR)
Collection date and time (derived)	7 JAN 2021 08:04

US3252215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	08:03
Collection Date and Time (derived)	7 JAN 2021 08:03

US3252215

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	07:21 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 07:21
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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)	4 FEB 2021
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 08:45
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252215

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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.

US3252215

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 08:13 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 08:13

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

US3252215

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252215

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:24:50

Generated On: 09 Jun 2021 16:11:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252215

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:45 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 07:45
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252215

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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.

US3252215

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	07:49 (24 HR)
Collection date and time (derived)	4 MAR 2021 07:49

US3252215

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Apr 2021 18:51:18

Generated On: 09 Jun 2021 16:11:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 May 2021 00:27:35

Generated On: 09 Jun 2021 16:11:44

AEID	USA-US108-2021-MRNA-1273-P30 1000018
Adverse event	WORSENING PERIPHERAL ARTERY DISEASE
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)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	23 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	24 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	339 of 2031

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 May 2021 00:27:35

Generated On: 09 Jun 2021 16:11:44

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 May 2021 00:27:35

Generated On: 09 Jun 2021 16:11:44

SUBJECT REPORTED ON HIS
SAFETY CALL HE RECENTLY
HAD A SCHEDULED
PROCEDURE DONE ON THE
23RD OF MAR 2021. SUBJECT
HAD A HISTORY OF
PERIPHERAL ARTERY DISEASE
AND RECENTLY HAD A
SCHEDULED FEMORAL
ENDARTERECTOMY DONE ON
THE 23RD OF MAR 2021. HE
WAS ADMITTED FOR OVER
NIGHT OBSERVATION AND
WAS DISCHARGED ON THE
MORNING OF THE 24TH OF
MAR. SUBJECT WAS
PRESCRIBED XARELTO 2.5 MG
BY MOUTH TWICE DAILY FOR
PROPHYLAXIS POST
PROCEDURE. SUBJECT IS
CURRENTLY DOING WELL AS
PER SUBJECT.

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)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

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

Yes ☒

No ☐

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

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication GLUCOVANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 5/500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication TRADJENTA

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	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 2017	
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"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication ADVAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 250/50

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 180

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Name of Medication XARELTO

Prophylaxis Yes ☒
No ☐

Indication POST FEMORAL
ENDARTERECTOMY

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

	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)		23 MAR 2021
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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 20:24:49

Generated On: 09 Jun 2021 16:11:44

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 18:51:19

Generated On: 09 Jun 2021 16:11:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 MAR 2021	FEMORAL ENDATERECTOMY	Adverse Event	

US3252215

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:44

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

US3252215

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:11:44

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 ☐

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 15:16
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

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 16:05
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

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5
Date of submission (Pre-filled from custom function)	16/APR/2021 13:24
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

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5
Date of submission (Pre-filled from custom function)	20/APR/2021 07:33
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

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 11:35:45

Generated On: 09 Jun 2021 16:11:44

SAEID	USA-US108-2021-MRNA-1273-P301000018
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)	5
Date of submission (Pre-filled from custom function)	27/APR/2021 08:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3252215 (Prod: Centex Studies Inc)

US3252215

Form: Participant Creation

Generated On: 09 Jun 2021 16:11:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'US3252215'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:09:56

US3252215

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:20
	(b) (4)	

US3252215

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:09:58

US3252215

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Clinic (Clinic)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:20
	(b) (4)	

US3252215

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'SCRN'	System	17 Aug 2020 20:00:20

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:09:59

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '65'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'YEARS'	System	17 Aug 2020 20:00:41

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '65'	System	17 Aug 2020 20:01:03

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Male (M)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'I'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:44

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Uche Ehiemua (b) (4)	17 Aug 2020 20:00:41
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Aug 2020'	System	17 Aug 2020 20:01:03

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '2020'	System	17 Aug 2020 20:01:03

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Amendment 2 (2)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:03
	(b) (4)	

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:09:58

US3252215

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'I'	System	17 Aug 2020 20:01:11

US3252215

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:11
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:11:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:31
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:27:02
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	18 Aug 2020 19:21:57
User entered 'Type 2 diabetes'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:21:55
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Jan 2010'	System	18 Aug 2020 19:21:55

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '2010'	System	18 Aug 2020 19:21:55

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:21:55

US3252215

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:21:55

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:27:05
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	18 Aug 2020 19:22:58
User entered 'Hypertension'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:10
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Jan 2010'	System	18 Aug 2020 19:22:10

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '2010'	System	18 Aug 2020 19:22:10

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:22:10

US3252215

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:22:10

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:27:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:27:05
Data point term sent to Coder	System	18 Aug 2020 19:23:00
User entered 'Asthma'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'UN UNK 2015'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:22:23
	(b) (4)	

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Jan 2015'	System	18 Aug 2020 19:22:23

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '2015'	System	18 Aug 2020 19:22:23

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:22:23

US3252215

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered empty.	System	18 Aug 2020 19:22:23

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 12:55:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 12:55:42
Data point term sent to Coder	System	01 Sep 2020 12:54:53
User entered 'Hernia Repair'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'UN Jan 1995'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'UN Jan 1995'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Jan 1995'	System	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '1995'	System	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'Jan 1995'	System	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '1995'	System	01 Sep 2020 12:54:33

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14:04'	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered '17 Aug 2020 14:04'	System	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '65' in	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:01:11

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '170.4' lb	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:01:11

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
Amendment Manager: User entered '28.41533'	System	17 Sep 2020 00:00:40
User entered '28.4'	System	18 Aug 2020 19:24:10
DataPoint set to visible.	System	17 Aug 2020 20:01:11

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'kg/m2'	System	18 Aug 2020 19:24:10
DataPoint set to visible.	System	17 Aug 2020 20:01:11

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:39:56
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Shannon Moyer (b) (4)	18 Aug 2020 19:24:14
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 19:24:10
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'bpm'	System	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'breaths/min'	System	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'mmHg'	System	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	18 Aug 2020 19:24:10
	(b) (4)	

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User entered 'mmHg'	System	18 Aug 2020 19:24:10

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48

US3252215

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48

US3252215

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:24:34
	(b) (4)	

US3252215

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:51:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:29:46
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:24:34

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Retired'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'I'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:50:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:25:20
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:33
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:33
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Clinic (Clinic)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:01:33
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'VISIT1'	System	17 Aug 2020 20:01:33

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:44

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:07:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:07:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:44:44
User entered '186713' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:44

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:44

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:12:30
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:12:30
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:12:30
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:12:30
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Uche Ehiemua (b) (4)	17 Aug 2020 20:12:30
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Nancy Torrence (b) (4)	29 Sep 2020 05:42:32
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:43:14

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify	(b) (4), (b) (6)	07 Sep 2020 14:18:24
' (Site from DM).		
Query 'Per CDM: per CCG's pages 15-16, Height and Joanna Gurrola Mahoney Weight should be entered as "ND". Please review and update else clarify	(b) (4)	01 Sep 2020 12:52:53
' answered with 'Corrected' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:52:42
User opened query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify	(b) (4), (b) (6)	31 Aug 2020 13:23:08
' (Site from DM).		
User entered empty.	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:52:42
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 14:18:24
Query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'Corrected' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:52:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:52:42
User opened query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:23:08
User entered empty.	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:52:42
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14:04'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '17 Aug 2020 14:04'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '98.2' F	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '91'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'bpm'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '15'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'breaths/min'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '123'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '74'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 14:18:24
Query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'Corrected' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:52:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:52:42
User opened query 'Per CDM: per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:23:08
User entered empty.	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:52:42
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:55:18
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4)	18 Aug 2020 19:28:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	18 Aug 2020 19:28:23
User entered '16:01'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '17 Aug 2020 16:01'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '98.0' F	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '89'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'bpm'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '15'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'breaths/min'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '146'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '84'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:23
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	18 Aug 2020 19:28:23

US3252215

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	26 Aug 2020 14:11:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:28:51

US3252215

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	26 Aug 2020 14:11:40
User entered '17 Aug 2020'	(b) (4)	
	Shannon Moyer (b) (4)	18 Aug 2020 19:28:51
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:31:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:31:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	18 Aug 2020 19:31:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 21:06:36
User entered empty.	Joanna Gurrola Mahoney (b) (4)	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Joanna Gurrola Mahoney (b) (4)	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Joanna Gurrola Mahoney (b) (4)	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 19:31:25
User entered empty.	System	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '15:11'	Joanna Gurrola Mahoney (b) (4)	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '17 Aug 2020 15:11'	System	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	18 Aug 2020 19:31:25
User entered empty.	(b) (4)	17 Aug 2020 21:06:36
	Joanna Gurrola Mahoney (b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'ONCE'	System	18 Aug 2020 19:31:25
User entered empty.	System	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 19:31:25
User entered empty.	System	17 Aug 2020 21:06:36

US3252215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:31:45
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	18 Aug 2020 19:31:45
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14:50'	Shannon Moyer (b) (4)	18 Aug 2020 19:31:45
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '17 Aug 2020 14:50'	System	18 Aug 2020 19:31:45

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	18 Aug 2020 19:32:01
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:32:01

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:32:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:32:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	18 Aug 2020 19:32:14
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:32:01
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:32:01

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14:40'	Shannon Moyer (b) (4)	18 Aug 2020 19:32:01
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '17 Aug 2020 14:40'	System	18 Aug 2020 19:32:01

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:32:01

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:32:01
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:32:01
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered empty.	System	18 Aug 2020 19:32:01

US3252215

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:32:22
	(b) (4)	

US3252215

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	18 Aug 2020 19:32:22

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:07:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9b5854ae-b9ca-45ec-a69d-f00b0d76588e'	System	17 Aug 2020 21:07:52
User entered 'Yes (Y)'	System	17 Aug 2020 21:07:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:07:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9b5854ae-b9ca-45ec-a69d-f00b0d76588e'	System	17 Aug 2020 21:07:52
User entered '98.0'	System	17 Aug 2020 21:07:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:07:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9b5854ae-b9ca-45ec-a69d-f00b0d76588e'	System	17 Aug 2020 21:07:52
User entered 'No (N)'	System	17 Aug 2020 21:07:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:07:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9b5854ae-b9ca-45ec-a69d-f00b0d76588e'	System	17 Aug 2020 21:07:52
User entered '17 Aug 2020 16:07'	System	17 Aug 2020 21:07:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:52:02', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ac9a6b27-ae6e-4e9e-8e27-7c0d2fd42496'	System	18 Aug 2020 00:55:49
User entered 'Yes (Y)'	System	18 Aug 2020 00:55:49

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:55:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ac9a6b27-ae6e-4e9e-8e27-7c0d2fd42496'	System	18 Aug 2020 00:55:49
User entered '93.3'	System	18 Aug 2020 00:55:49

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:55:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ac9a6b27-ae6e-4e9e-8e27-7c0d2fd42496'	System	18 Aug 2020 00:55:49
User entered 'No (N)'	System	18 Aug 2020 00:55:49

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:55:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ac9a6b27-ae6e-4e9e-8e27-7c0d2fd42496'	System	18 Aug 2020 00:55:49
User entered '17 Aug 2020 19:55'	System	18 Aug 2020 00:55:49

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:56'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 2'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:03:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8967eb24-b900-4e1f-acf5-15ffa71eaa88'	System	18 Aug 2020 17:04:52
User entered 'Yes (Y)'	System	18 Aug 2020 17:04:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:03:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8967eb24-b900-4e1f-acf5-15ffa71eaa88'	System	18 Aug 2020 17:04:52
User entered '98.1'	System	18 Aug 2020 17:04:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:04:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8967eb24-b900-4e1f-acf5-15ffa71eaa88'	System	18 Aug 2020 17:04:52
User entered 'No (N)'	System	18 Aug 2020 17:04:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:04:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8967eb24-b900-4e1f-acf5-15ffa71eaa88'	System	18 Aug 2020 17:04:52
User entered '18 Aug 2020 12:04'	System	18 Aug 2020 17:04:52

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 3'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:03:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7e8b601e-36a9-4113-b9bb-9ef37af74281'	System	19 Aug 2020 17:04:31
User entered 'Yes (Y)'	System	19 Aug 2020 17:04:31

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:03:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7e8b601e-36a9-4113-b9bb-9ef37af74281'	System	19 Aug 2020 17:04:31
User entered '97.3'	System	19 Aug 2020 17:04:31

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:03:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7e8b601e-36a9-4113-b9bb-9ef37af74281'	System	19 Aug 2020 17:04:31
User entered 'No (N)'	System	19 Aug 2020 17:04:31

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:04:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7e8b601e-36a9-4113-b9bb-9ef37af74281'	System	19 Aug 2020 17:04:31
User entered '19 Aug 2020 12:04'	System	19 Aug 2020 17:04:31

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 4'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:04:50', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24da9a72-bd77-46f2-a41e-be00e5bb313c'	System	20 Aug 2020 17:05:54
User entered 'Yes (Y)'	System	20 Aug 2020 17:05:54

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:05:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24da9a72-bd77-46f2-a41e-be00e5bb313c'	System	20 Aug 2020 17:05:54
User entered '97.7'	System	20 Aug 2020 17:05:54

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:05:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24da9a72-bd77-46f2-a41e-be00e5bb313c'	System	20 Aug 2020 17:05:54
User entered 'No (N)'	System	20 Aug 2020 17:05:54

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:05:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24da9a72-bd77-46f2-a41e-be00e5bb313c'	System	20 Aug 2020 17:05:54
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 17:05:54

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 5'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:10:47', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '192483a1-46f7-4e9b-b0a7-0b8a0377e866'	System	21 Aug 2020 17:11:51
User entered 'Yes (Y)'	System	21 Aug 2020 17:11:51

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:11:05', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '192483a1-46f7-4e9b-b0a7-0b8a0377e866'	System	21 Aug 2020 17:11:51
User entered '97.8'	System	21 Aug 2020 17:11:51

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:11:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '192483a1-46f7-4e9b-b0a7-0b8a0377e866'	System	21 Aug 2020 17:11:51
User entered 'No (N)'	System	21 Aug 2020 17:11:51

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:11:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '192483a1-46f7-4e9b-b0a7-0b8a0377e866'	System	21 Aug 2020 17:11:51
User entered '21 Aug 2020 12:11'	System	21 Aug 2020 17:11:51

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 6'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:05:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e9b2e285-3ce9-457a-ad8d-7819cad75691'	System	22 Aug 2020 17:06:09
User entered 'Yes (Y)'	System	22 Aug 2020 17:06:09

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:05:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e9b2e285-3ce9-457a-ad8d-7819cad75691'	System	22 Aug 2020 17:06:09
User entered '98.1'	System	22 Aug 2020 17:06:09

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:05:35', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e9b2e285-3ce9-457a-ad8d-7819cad75691'	System	22 Aug 2020 17:06:09
User entered 'No (N)'	System	22 Aug 2020 17:06:09

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:06:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e9b2e285-3ce9-457a-ad8d-7819cad75691'	System	22 Aug 2020 17:06:09
User entered '22 Aug 2020 12:06'	System	22 Aug 2020 17:06:09

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 7'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:03:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24e709b6-16aa-4d6b-9d63-c7287d9ab2bd'	System	23 Aug 2020 18:04:43
User entered 'Yes (Y)'	System	23 Aug 2020 18:04:43

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:04:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24e709b6-16aa-4d6b-9d63-c7287d9ab2bd' User entered '97.7'	System	23 Aug 2020 18:04:43
	System	23 Aug 2020 18:04:43

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:04:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24e709b6-16aa-4d6b-9d63-c7287d9ab2bd'	System	23 Aug 2020 18:04:43
User entered 'No (N)'	System	23 Aug 2020 18:04:43

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:04:47', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '24e709b6-16aa-4d6b-9d63-c7287d9ab2bd'	System	23 Aug 2020 18:04:43
User entered '23 Aug 2020 13:04'	System	23 Aug 2020 18:04:43

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:01', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a2319ce-e69b-4863-aa47-bf96cf19a719'	System	17 Aug 2020 21:08:13
User entered 'None (1)'	System	17 Aug 2020 21:08:13

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a2319ce-e69b-4863-aa47-bf96cf19a719'	System	17 Aug 2020 21:08:13
User entered 'No (N)'	System	17 Aug 2020 21:08:13

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:06', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a2319ce-e69b-4863-aa47-bf96cf19a719'	System	17 Aug 2020 21:08:13
User entered 'No (N)'	System	17 Aug 2020 21:08:13

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a2319ce-e69b-4863-aa47-bf96cf19a719'	System	17 Aug 2020 21:08:13
User entered 'None (1)'	System	17 Aug 2020 21:08:13

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a2319ce-e69b-4863-aa47-bf96cf19a719'	System	17 Aug 2020 21:08:13
User entered '17 Aug 2020 16:08'	System	17 Aug 2020 21:08:13

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:56:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '73910869-d9b9-4fe0-8e7f-46f9800f1576'	System	18 Aug 2020 00:57:28
User entered 'None (1)'	System	18 Aug 2020 00:57:28

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:56:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '73910869-d9b9-4fe0-8e7f-46f9800f1576'	System	18 Aug 2020 00:57:28
User entered 'No (N)'	System	18 Aug 2020 00:57:28

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:56:36', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '73910869-d9b9-4fe0-8e7f-46f9800f1576'	System	18 Aug 2020 00:57:28
User entered 'No (N)'	System	18 Aug 2020 00:57:28

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:56:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '73910869-d9b9-4fe0-8e7f-46f9800f1576'	System	18 Aug 2020 00:57:28
User entered 'None (1)'	System	18 Aug 2020 00:57:28

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:57:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '73910869-d9b9-4fe0-8e7f-46f9800f1576'	System	18 Aug 2020 00:57:28
User entered '17 Aug 2020 19:57'	System	18 Aug 2020 00:57:28

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:56'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 2'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:05:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'a356d158-ce67-4862-a7c5-b47c038be9cf'	System	18 Aug 2020 17:06:23
User entered 'None (1)'	System	18 Aug 2020 17:06:23

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:05:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'a356d158-ce67-4862-a7c5-b47c038be9cf'	System	18 Aug 2020 17:06:23
User entered 'No (N)'	System	18 Aug 2020 17:06:23

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:05:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'a356d158-ce67-4862-a7c5-b47c038be9cf'	System	18 Aug 2020 17:06:23
User entered 'No (N)'	System	18 Aug 2020 17:06:23

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:05:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'a356d158-ce67-4862-a7c5-b47c038be9cf'	System	18 Aug 2020 17:06:23
User entered 'None (1)'	System	18 Aug 2020 17:06:23

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:06:21', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'a356d158-ce67-4862-a7c5-b47c038be9cf'	System	18 Aug 2020 17:06:23
User entered '18 Aug 2020 12:06'	System	18 Aug 2020 17:06:23

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 3'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:04:45', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0f149145-4898-4475-81af-7093c180c28b'	System	19 Aug 2020 17:05:48
User entered 'None (1)'	System	19 Aug 2020 17:05:48

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:04:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0f149145-4898-4475-81af-7093c180c28b'	System	19 Aug 2020 17:05:48
User entered 'No (N)'	System	19 Aug 2020 17:05:48

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:05:08', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0f149145-4898-4475-81af-7093c180c28b'	System	19 Aug 2020 17:05:48
User entered 'No (N)'	System	19 Aug 2020 17:05:48

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:05:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0f149145-4898-4475-81af-7093c180c28b'	System	19 Aug 2020 17:05:48
User entered 'None (1)'	System	19 Aug 2020 17:05:48

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:05:46', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0f149145-4898-4475-81af-7093c180c28b'	System	19 Aug 2020 17:05:48
User entered '19 Aug 2020 12:05'	System	19 Aug 2020 17:05:48

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 4'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:06:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8ded8de1-beaa-4fd8-bfbc-cb262a05b093'	System	20 Aug 2020 17:07:59
User entered 'None (1)'	System	20 Aug 2020 17:07:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:06:39', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8ded8de1-beaa-4fd8-bfbc-cb262a05b093'	System	20 Aug 2020 17:07:59
User entered 'No (N)'	System	20 Aug 2020 17:07:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:06:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8ded8de1-beaa-4fd8-bfbc-cb262a05b093'	System	20 Aug 2020 17:07:59
User entered 'No (N)'	System	20 Aug 2020 17:07:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:07:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8ded8de1-beaa-4fd8-bfbc-cb262a05b093'	System	20 Aug 2020 17:07:59
User entered 'None (1)'	System	20 Aug 2020 17:07:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:07:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8ded8de1-beaa-4fd8-bfbc-cb262a05b093'	System	20 Aug 2020 17:07:59
User entered '20 Aug 2020 12:07'	System	20 Aug 2020 17:07:59

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 5'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:11:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b6088731-f998-4da4-a0f5-119d4f5f42a4'	System	21 Aug 2020 17:13:04
User entered 'None (1)'	System	21 Aug 2020 17:13:04

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:12:01', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b6088731-f998-4da4-a0f5-119d4f5f42a4'	System	21 Aug 2020 17:13:04
User entered 'No (N)'	System	21 Aug 2020 17:13:04

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:12:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b6088731-f998-4da4-a0f5-119d4f5f42a4'	System	21 Aug 2020 17:13:04
User entered 'No (N)'	System	21 Aug 2020 17:13:04

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:12:21', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b6088731-f998-4da4-a0f5-119d4f5f42a4'	System	21 Aug 2020 17:13:04
User entered 'None (1)'	System	21 Aug 2020 17:13:04

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:12:50', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b6088731-f998-4da4-a0f5-119d4f5f42a4'	System	21 Aug 2020 17:13:04
User entered '21 Aug 2020 12:12'	System	21 Aug 2020 17:13:04

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 6'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:06:34', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8aa8b952-24cc-45e5-bb2b-d086e9630a02'	System	22 Aug 2020 17:07:55
User entered 'None (1)'	System	22 Aug 2020 17:07:55

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:06:45', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8aa8b952-24cc-45e5-bb2b-d086e9630a02'	System	22 Aug 2020 17:07:55
User entered 'No (N)'	System	22 Aug 2020 17:07:55

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:06:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8aa8b952-24cc-45e5-bb2b-d086e9630a02'	System	22 Aug 2020 17:07:55
User entered 'No (N)'	System	22 Aug 2020 17:07:55

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:07:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8aa8b952-24cc-45e5-bb2b-d086e9630a02'	System	22 Aug 2020 17:07:55
User entered 'None (1)'	System	22 Aug 2020 17:07:55

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:07:57', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8aa8b952-24cc-45e5-bb2b-d086e9630a02'	System	22 Aug 2020 17:07:55
User entered '22 Aug 2020 12:07'	System	22 Aug 2020 17:07:55

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 7'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:04:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '075b1153-ac77-4b21-b86f-82e9a534dfe6'	System	23 Aug 2020 18:06:16
User entered 'None (1)'	System	23 Aug 2020 18:06:16

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:05:08', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '075b1153-ac77-4b21-b86f-82e9a534dfe6'	System	23 Aug 2020 18:06:16
User entered 'No (N)'	System	23 Aug 2020 18:06:16

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:05:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '075b1153-ac77-4b21-b86f-82e9a534dfe6'	System	23 Aug 2020 18:06:16
User entered 'No (N)'	System	23 Aug 2020 18:06:16

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:05:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '075b1153-ac77-4b21-b86f-82e9a534dfe6'	System	23 Aug 2020 18:06:16
User entered 'None (1)'	System	23 Aug 2020 18:06:16

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:06:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '075b1153-ac77-4b21-b86f-82e9a534dfe6'	System	23 Aug 2020 18:06:16
User entered '23 Aug 2020 13:06'	System	23 Aug 2020 18:06:16

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:29', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'None (0)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered 'No (N)'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T16:08:34', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01392b7d-94db-46b6-b065-8c650e5d8729'	System	17 Aug 2020 21:08:31
User entered '17 Aug 2020 16:08'	System	17 Aug 2020 21:08:31

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:06', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:47:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'None (0)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:48:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered 'No (N)'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-17T19:48:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '779a35a0-8cd6-48f9-925f-52f27bd9ae95'	System	18 Aug 2020 00:48:49
User entered '17 Aug 2020 19:48'	System	18 Aug 2020 00:48:49

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Aug 2020 18:56'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 2'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:06:36', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:06:45', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:07:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:07:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:07:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:07:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'None (0)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:08:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered 'No (N)'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-18T12:09:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'cdc06cd4-be0f-4f03-bac0-8beed2375974'	System	18 Aug 2020 17:09:16
User entered '18 Aug 2020 12:09'	System	18 Aug 2020 17:09:16

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 3'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:05:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:06:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:06:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:06:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:07:00', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:07:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'None (0)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:07:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered 'No (N)'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-19T12:08:00', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '6c07c5d0-7999-4b4f-8fa8-ca44943d6a37'	System	19 Aug 2020 17:08:03
User entered '19 Aug 2020 12:08'	System	19 Aug 2020 17:08:03

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 4'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:08:09', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:08:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:08:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:08:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:09:03', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:09:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'None (0)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:09:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered 'No (N)'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-20T12:10:02', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62d2a3f5-bb43-410b-a11e-370288a301c9'	System	20 Aug 2020 17:10:05
User entered '20 Aug 2020 12:10'	System	20 Aug 2020 17:10:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 5'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:34', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:39', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'None (0)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:13:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered 'No (N)'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-21T12:14:06', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c7d8a834-e65c-4bba-a8df-e0490bde116e'	System	21 Aug 2020 17:14:05
User entered '21 Aug 2020 12:14'	System	21 Aug 2020 17:14:05

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 6'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:08:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:08:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:08:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:09:03', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:09:13', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:09:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'None (0)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:09:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered 'No (N)'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-22T12:10:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '975f6437-2a01-4548-ad5c-8bbb0a929e81'	System	22 Aug 2020 17:10:21
User entered '22 Aug 2020 12:10'	System	22 Aug 2020 17:10:21

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 7'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:06:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:06:56', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:07:03', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:07:23', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:07:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:07:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'None (0)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:08:08', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered 'No (N)'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-08-23T13:08:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '674369b7-c93a-4c73-93d2-a4c4fb074d9d'	System	23 Aug 2020 18:08:55
User entered '23 Aug 2020 13:08'	System	23 Aug 2020 18:08:55

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 21:06:36

US3252215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Aug 2020 14:12:12
	(b) (4)	

US3252215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '25 Aug 2020'	Shannon Moyer (b) (4)	26 Aug 2020 14:12:12
	(b) (4)	

US3252215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	26 Aug 2020 14:12:12
	(b) (4)	

US3252215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	26 Aug 2020 14:12:12
	(b) (4)	

US3252215

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Aug 2020 14:12:18
	(b) (4)	

US3252215

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	26 Aug 2020 14:12:18

US3252215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 03:35:40
	(b) (4)	

US3252215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '31 Aug 2020'	Shannon Moyer (b) (4)	02 Sep 2020 03:35:40
	(b) (4)	

US3252215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	02 Sep 2020 03:35:40
	(b) (4)	

US3252215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 03:35:40
	(b) (4)	

US3252215

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 03:35:47
	(b) (4)	

US3252215

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '1'	System	02 Sep 2020 03:35:47

US3252215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	09 Sep 2020 03:48:17
	(b) (4)	

US3252215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '8 Sep 2020'	Nancy Torrence (b) (4)	09 Sep 2020 03:48:17
	(b) (4)	

US3252215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	09 Sep 2020 03:48:17
	(b) (4)	

US3252215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	09 Sep 2020 03:48:17
	(b) (4)	

US3252215

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	09 Sep 2020 03:48:25
	(b) (4)	

US3252215

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	09 Sep 2020 03:48:25

US3252215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 13:29:46

US3252215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 13:29:46

US3252215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 13:29:46

US3252215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'VISIT2'	System	14 Sep 2020 13:29:46

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14 Sep 2020'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:11'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '14 Sep 2020 08:11'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '98.6' F	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '81'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'bpm'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '16'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'breaths/min'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '123'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '74'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14 Sep 2020'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '09:25' reason for change: Data Entry	Shannon Moyer (b) (4)	15 Sep 2020 07:42:32
Error	(b) (4)	
User entered '09:24'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '14 Sep 2020 09:25'	System	15 Sep 2020 07:42:32
User entered '14 Sep 2020 09:24'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '97.8' F	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '79'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'bpm'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '15'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'breaths/min'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '105'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '61'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:36
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	15 Sep 2020 03:06:36

US3252215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	15 Sep 2020 03:06:50
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	15 Sep 2020 03:06:50
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Joanna Gurrola Mahoney	14 Sep 2020 13:54:04
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14 Sep 2020'	Joanna Gurrola Mahoney	14 Sep 2020 13:54:04
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:47'	Joanna Gurrola Mahoney	14 Sep 2020 13:54:04
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '14 Sep 2020 08:47'	System	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	14 Sep 2020 13:54:04
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'ONCE'	System	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 13:54:04

US3252215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	15 Sep 2020 03:07:47
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:59:31
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Samples have been shipped. AWB Number: 917903344858' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:56:09
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:25:01
User entered '14 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	15 Sep 2020 03:07:47

US3252215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:35'	Shannon Moyer (b) (4)	15 Sep 2020 03:07:47
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '14 Sep 2020 08:35'	System	15 Sep 2020 03:07:47

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '14 Sep 2020'	Shannon Moyer (b) (4)	15 Sep 2020 03:08:33
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	15 Sep 2020 03:08:33

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	15 Sep 2020 03:08:33
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:28'	Shannon Moyer (b) (4)	15 Sep 2020 03:08:33
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '14 Sep 2020 08:28'	System	15 Sep 2020 03:08:33

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	15 Sep 2020 03:08:33

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Shannon Moyer (b) (4)	15 Sep 2020 03:08:33
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Shannon Moyer (b) (4)	15 Sep 2020 03:08:33
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered empty.	System	15 Sep 2020 03:08:33

US3252215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	15 Sep 2020 03:08:39
	(b) (4)	

US3252215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	15 Sep 2020 03:08:39

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:34:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '45282bf5-62f4-4caf-867a-16da2f997761'	System	14 Sep 2020 14:35:14
User entered 'Yes (Y)'	System	14 Sep 2020 14:35:14

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:34:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '45282bf5-62f4-4caf-867a-16da2f997761'	System	14 Sep 2020 14:35:14
User entered '97.8'	System	14 Sep 2020 14:35:14

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:34:56', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '45282bf5-62f4-4caf-867a-16da2f997761'	System	14 Sep 2020 14:35:14
User entered 'No (N)'	System	14 Sep 2020 14:35:14

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:35:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '45282bf5-62f4-4caf-867a-16da2f997761'	System	14 Sep 2020 14:35:14
User entered '14 Sep 2020 09:35'	System	14 Sep 2020 14:35:14

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 09:07'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:12:35', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f6446e4b-d902-40ba-ac64-becde3237a24'	System	14 Sep 2020 21:13:17
User entered 'Yes (Y)'	System	14 Sep 2020 21:13:17

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:12:46', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f6446e4b-d902-40ba-ac64-becde3237a24'	System	14 Sep 2020 21:13:17
User entered '98.0'	System	14 Sep 2020 21:13:17

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:12:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f6446e4b-d902-40ba-ac64-becde3237a24'	System	14 Sep 2020 21:13:17
User entered 'No (N)'	System	14 Sep 2020 21:13:17

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:13:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f6446e4b-d902-40ba-ac64-becde3237a24'	System	14 Sep 2020 21:13:17
User entered '14 Sep 2020 16:13'	System	14 Sep 2020 21:13:17

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 12:32'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 2'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:22:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b52bd6ea-bd18-4001-9bcb-5f7831d683cf'	System	15 Sep 2020 18:23:15
User entered 'Yes (Y)'	System	15 Sep 2020 18:23:15

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:22:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b52bd6ea-bd18-4001-9bcb-5f7831d683cf'	System	15 Sep 2020 18:23:15
User entered '98.3'	System	15 Sep 2020 18:23:15

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:22:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b52bd6ea-bd18-4001-9bcb-5f7831d683cf'	System	15 Sep 2020 18:23:15
User entered 'No (N)'	System	15 Sep 2020 18:23:15

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:23:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b52bd6ea-bd18-4001-9bcb-5f7831d683cf'	System	15 Sep 2020 18:23:15
User entered '15 Sep 2020 13:23'	System	15 Sep 2020 18:23:15

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 3'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:02:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'be822172-12be-4757-9c22-0217e5aa0ad6'	System	16 Sep 2020 17:04:23
User entered 'Yes (Y)'	System	16 Sep 2020 17:04:23

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:02:56', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'be822172-12be-4757-9c22-0217e5aa0ad6'	System	16 Sep 2020 17:04:23
User entered '97.9'	System	16 Sep 2020 17:04:23

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:09', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'be822172-12be-4757-9c22-0217e5aa0ad6'	System	16 Sep 2020 17:04:23
User entered 'No (N)'	System	16 Sep 2020 17:04:23

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'be822172-12be-4757-9c22-0217e5aa0ad6'	System	16 Sep 2020 17:04:23
User entered '16 Sep 2020 12:03'	System	16 Sep 2020 17:04:23

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 4'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:54:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '434df62-c2c6-47c0-9058-a855de31433f'	System	17 Sep 2020 20:54:58
User entered 'Yes (Y)'	System	17 Sep 2020 20:54:58

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:54:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '434dfe62-c2c6-47c0-9058-a855de31433f'	System	17 Sep 2020 20:54:58
User entered '98.0'	System	17 Sep 2020 20:54:58

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:54:44', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '434dfe62-c2c6-47c0-9058-a855de31433f'	System	17 Sep 2020 20:54:58
User entered 'No (N)'	System	17 Sep 2020 20:54:58

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:54:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '434df62-c2c6-47c0-9058-a855de31433f'	System	17 Sep 2020 20:54:58
User entered '17 Sep 2020 15:54'	System	17 Sep 2020 20:54:58

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 5'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:06:47', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aae3fe62-92d3-4a90-a66a-e76e1a2d2f9f'	System	18 Sep 2020 17:07:40
User entered 'Yes (Y)'	System	18 Sep 2020 17:07:40

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:07:05', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aae3fe62-92d3-4a90-a66a-e76e1a2d2f9f'	System	18 Sep 2020 17:07:40
User entered '98.2'	System	18 Sep 2020 17:07:40

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:07:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aae3fe62-92d3-4a90-a66a-e76e1a2d2f9f'	System	18 Sep 2020 17:07:40
User entered 'No (N)'	System	18 Sep 2020 17:07:40

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:07:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aae3fe62-92d3-4a90-a66a-e76e1a2d2f9f'	System	18 Sep 2020 17:07:40
User entered '18 Sep 2020 12:07'	System	18 Sep 2020 17:07:40

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 6'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:02:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8d4aa862-0816-402f-8fe4-bcde27683a9a'	System	19 Sep 2020 22:03:19
User entered 'Yes (Y)'	System	19 Sep 2020 22:03:19

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:02:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8d4aa862-0816-402f-8fe4-bcde27683a9a'	System	19 Sep 2020 22:03:19
User entered '97.8'	System	19 Sep 2020 22:03:19

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:02:39', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8d4aa862-0816-402f-8fe4-bcde27683a9a'	System	19 Sep 2020 22:03:19
User entered 'No (N)'	System	19 Sep 2020 22:03:19

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:03:13', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8d4aa862-0816-402f-8fe4-bcde27683a9a'	System	19 Sep 2020 22:03:19
User entered '19 Sep 2020 17:03'	System	19 Sep 2020 22:03:19

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 7'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:57:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3e8e3c31-b74f-4bd9-b079-4531c6b0b888'	System	20 Sep 2020 17:58:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:58:55

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:58:06', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3e8e3c31-b74f-4bd9-b079-4531c6b0b888'	System	20 Sep 2020 17:58:55
User entered '98.0'	System	20 Sep 2020 17:58:55

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:58:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3e8e3c31-b74f-4bd9-b079-4531c6b0b888'	System	20 Sep 2020 17:58:55
User entered 'No (N)'	System	20 Sep 2020 17:58:55

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:58:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3e8e3c31-b74f-4bd9-b079-4531c6b0b888'	System	20 Sep 2020 17:58:55
User entered '20 Sep 2020 12:58'	System	20 Sep 2020 17:58:55

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:35:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c0cdd1b0-fea2-4fda-802c-0e7ad0ba782a'	System	14 Sep 2020 14:36:06
User entered 'None (1)'	System	14 Sep 2020 14:36:06

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:35:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c0cdd1b0-fea2-4fda-802c-0e7ad0ba782a'	System	14 Sep 2020 14:36:06
User entered 'No (N)'	System	14 Sep 2020 14:36:06

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:35:40', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c0cdd1b0-fea2-4fda-802c-0e7ad0ba782a'	System	14 Sep 2020 14:36:06
User entered 'No (N)'	System	14 Sep 2020 14:36:06

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:35:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c0cdd1b0-fea2-4fda-802c-0e7ad0ba782a'	System	14 Sep 2020 14:36:06
User entered 'None (1)'	System	14 Sep 2020 14:36:06

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:00', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c0cdd1b0-fea2-4fda-802c-0e7ad0ba782a'	System	14 Sep 2020 14:36:06
User entered '14 Sep 2020 09:36'	System	14 Sep 2020 14:36:06

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 09:07'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:13:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1d7cc613-321a-43c6-a0a3-e862d389023a'	System	14 Sep 2020 21:14:38
User entered 'None (1)'	System	14 Sep 2020 21:14:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:13:40', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1d7cc613-321a-43c6-a0a3-e862d389023a'	System	14 Sep 2020 21:14:38
User entered 'No (N)'	System	14 Sep 2020 21:14:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:13:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1d7cc613-321a-43c6-a0a3-e862d389023a'	System	14 Sep 2020 21:14:38
User entered 'No (N)'	System	14 Sep 2020 21:14:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:14:03', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1d7cc613-321a-43c6-a0a3-e862d389023a'	System	14 Sep 2020 21:14:38
User entered 'None (1)'	System	14 Sep 2020 21:14:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:14:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1d7cc613-321a-43c6-a0a3-e862d389023a'	System	14 Sep 2020 21:14:38
User entered '14 Sep 2020 16:14'	System	14 Sep 2020 21:14:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 12:32'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 2'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:23:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '876a1963-87bb-4745-b10d-6454b8358bdc'	System	15 Sep 2020 18:24:29
User entered 'None (1)'	System	15 Sep 2020 18:24:29

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:23:39', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '876a1963-87bb-4745-b10d-6454b8358bdc'	System	15 Sep 2020 18:24:29
User entered 'No (N)'	System	15 Sep 2020 18:24:29

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:23:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '876a1963-87bb-4745-b10d-6454b8358bdc'	System	15 Sep 2020 18:24:29
User entered 'No (N)'	System	15 Sep 2020 18:24:29

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:24:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '876a1963-87bb-4745-b10d-6454b8358bdc'	System	15 Sep 2020 18:24:29
User entered 'None (1)'	System	15 Sep 2020 18:24:29

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:24:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '876a1963-87bb-4745-b10d-6454b8358bdc'	System	15 Sep 2020 18:24:29
User entered '15 Sep 2020 13:24'	System	15 Sep 2020 18:24:29

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 3'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0fe92246-d466-4edb-8c07-319901be20d5'	System	16 Sep 2020 17:04:51
User entered 'None (1)'	System	16 Sep 2020 17:04:51

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:39', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0fe92246-d466-4edb-8c07-319901be20d5'	System	16 Sep 2020 17:04:51
User entered 'No (N)'	System	16 Sep 2020 17:04:51

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:46', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0fe92246-d466-4edb-8c07-319901be20d5'	System	16 Sep 2020 17:04:51
User entered 'No (N)'	System	16 Sep 2020 17:04:51

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:03:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0fe92246-d466-4edb-8c07-319901be20d5'	System	16 Sep 2020 17:04:51
User entered 'None (1)'	System	16 Sep 2020 17:04:51

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:04:29', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0fe92246-d466-4edb-8c07-319901be20d5'	System	16 Sep 2020 17:04:51
User entered '16 Sep 2020 12:04'	System	16 Sep 2020 17:04:51

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 4'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:55:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fc32e839-3d58-4d9e-b714-9c90e35e2f2f'	System	17 Sep 2020 20:56:12
User entered 'None (1)'	System	17 Sep 2020 20:56:12

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:55:23', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fc32e839-3d58-4d9e-b714-9c90e35e2f2f'	System	17 Sep 2020 20:56:12
User entered 'No (N)'	System	17 Sep 2020 20:56:12

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:55:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fc32e839-3d58-4d9e-b714-9c90e35e2f2f'	System	17 Sep 2020 20:56:12
User entered 'No (N)'	System	17 Sep 2020 20:56:12

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:55:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fc32e839-3d58-4d9e-b714-9c90e35e2f2f'	System	17 Sep 2020 20:56:12
User entered 'None (1)'	System	17 Sep 2020 20:56:12

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:56:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fc32e839-3d58-4d9e-b714-9c90e35e2f2f'	System	17 Sep 2020 20:56:12
User entered '17 Sep 2020 15:56'	System	17 Sep 2020 20:56:12

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 5'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:07:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e08cfd83-de8f-45d3-a67f-1aa2c7360ac6'	System	18 Sep 2020 17:08:44
User entered 'None (1)'	System	18 Sep 2020 17:08:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:08:00', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e08cfd83-de8f-45d3-a67f-1aa2c7360ac6'	System	18 Sep 2020 17:08:44
User entered 'No (N)'	System	18 Sep 2020 17:08:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:08:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e08cfd83-de8f-45d3-a67f-1aa2c7360ac6'	System	18 Sep 2020 17:08:44
User entered 'No (N)'	System	18 Sep 2020 17:08:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:08:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e08cfd83-de8f-45d3-a67f-1aa2c7360ac6'	System	18 Sep 2020 17:08:44
User entered 'None (1)'	System	18 Sep 2020 17:08:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:08:46', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e08cfd83-de8f-45d3-a67f-1aa2c7360ac6'	System	18 Sep 2020 17:08:44
User entered '18 Sep 2020 12:08'	System	18 Sep 2020 17:08:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 6'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:03:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '09afd4a7-7f89-41f4-84a6-ebb519639168'	System	19 Sep 2020 22:04:38
User entered 'None (1)'	System	19 Sep 2020 22:04:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:03:46', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '09afd4a7-7f89-41f4-84a6-ebb519639168'	System	19 Sep 2020 22:04:38
User entered 'No (N)'	System	19 Sep 2020 22:04:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '09afd4a7-7f89-41f4-84a6-ebb519639168'	System	19 Sep 2020 22:04:38
User entered 'No (N)'	System	19 Sep 2020 22:04:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '09afd4a7-7f89-41f4-84a6-ebb519639168'	System	19 Sep 2020 22:04:38
User entered 'None (1)'	System	19 Sep 2020 22:04:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:35', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '09afd4a7-7f89-41f4-84a6-ebb519639168'	System	19 Sep 2020 22:04:38
User entered '19 Sep 2020 17:04'	System	19 Sep 2020 22:04:38

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 7'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:02', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a4e3d04-fa74-4aea-99bb-adc4aecb0dd6'	System	20 Sep 2020 17:59:44
User entered 'None (1)'	System	20 Sep 2020 17:59:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a4e3d04-fa74-4aea-99bb-adc4aecb0dd6'	System	20 Sep 2020 17:59:44
User entered 'No (N)'	System	20 Sep 2020 17:59:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:23', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a4e3d04-fa74-4aea-99bb-adc4aecb0dd6'	System	20 Sep 2020 17:59:44
User entered 'No (N)'	System	20 Sep 2020 17:59:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a4e3d04-fa74-4aea-99bb-adc4aecb0dd6'	System	20 Sep 2020 17:59:44
User entered 'None (1)'	System	20 Sep 2020 17:59:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:40', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7a4e3d04-fa74-4aea-99bb-adc4aecb0dd6'	System	20 Sep 2020 17:59:44
User entered '20 Sep 2020 12:59'	System	20 Sep 2020 17:59:44

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:09', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:36:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'None (0)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:37:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered 'No (N)'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T09:37:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '01298a82-508a-4c28-918c-f9c0f38d9757'	System	14 Sep 2020 14:37:32
User entered '14 Sep 2020 09:37'	System	14 Sep 2020 14:37:32

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 09:07'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:14:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:14:53', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:14:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:15:06', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:15:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:15:29', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'None (0)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:15:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered 'No (N)'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-14T16:16:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ebda4ffe-6987-4870-8153-a7771b7846b7'	System	14 Sep 2020 21:16:13
User entered '14 Sep 2020 16:16'	System	14 Sep 2020 21:16:13

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '14 Sep 2020 12:32'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 2'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:24:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:25:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:25:40', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:25:56', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:26:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:26:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'None (0)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:26:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered 'No (N)'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-15T13:27:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'e23ba72e-b88b-488f-91df-78c0692d4b1a'	System	15 Sep 2020 18:27:40
User entered '15 Sep 2020 13:27'	System	15 Sep 2020 18:27:40

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 3'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:04:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:04:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:05:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:05:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:05:29', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:05:36', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'None (0)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:05:50', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered 'No (N)'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-16T12:06:13', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8be872e3-6de9-4835-8e5a-cd3c1feb9d1f'	System	16 Sep 2020 17:06:24
User entered '16 Sep 2020 12:06'	System	16 Sep 2020 17:06:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 4'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:56:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:56:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:56:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:56:57', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:57:02', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:57:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'None (0)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:57:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered 'No (N)'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-17T15:57:50', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '63b59f4f-ed0a-4073-9c3d-f01cd24984e3'	System	17 Sep 2020 20:57:51
User entered '17 Sep 2020 15:57'	System	17 Sep 2020 20:57:51

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 5'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:34', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'None (0)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:09:51', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered 'No (N)'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-18T12:10:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'c9345d5c-8567-4d2a-8a51-904f43245a8e'	System	18 Sep 2020 17:10:25
User entered '18 Sep 2020 12:10'	System	18 Sep 2020 17:10:25

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 6'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:44', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:04:57', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:05:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:05:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:05:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'None (0)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:05:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered 'No (N)'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-19T17:05:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0d8799d2-d9ad-4848-b816-35a145c9ccc6'	System	19 Sep 2020 22:05:45
User entered '19 Sep 2020 17:05'	System	19 Sep 2020 22:05:45

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	14 Sep 2020 13:54:04
User entered 'Day 7'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:49', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:53', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T12:59:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T13:00:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T13:00:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T13:00:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'None (0)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T13:00:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered 'No (N)'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-09-20T13:01:20', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '9cb97994-1896-4031-8349-3c19ca913141'	System	20 Sep 2020 18:01:24
User entered '20 Sep 2020 13:01'	System	20 Sep 2020 18:01:24

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:54:04

US3252215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:54:04

US3252215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 01:47:10
	(b) (4)	

US3252215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 01:47:10
	(b) (4)	

US3252215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	22 Sep 2020 01:47:10
	(b) (4)	

US3252215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 01:47:10
	(b) (4)	

US3252215

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 01:47:14
	(b) (4)	

US3252215

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	22 Sep 2020 01:47:14

US3252215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 05:42:49
	(b) (4)	

US3252215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 05:42:49
	(b) (4)	

US3252215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	29 Sep 2020 05:42:49
	(b) (4)	

US3252215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	29 Sep 2020 05:42:49
	(b) (4)	

US3252215

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 05:42:53
	(b) (4)	

US3252215

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	29 Sep 2020 05:42:53

US3252215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Oct 2020 03:44:53
	(b) (4)	

US3252215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '5 Oct 2020'	Nancy Torrence (b) (4)	06 Oct 2020 03:44:53
	(b) (4)	

US3252215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	06 Oct 2020 03:44:53
	(b) (4)	

US3252215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	06 Oct 2020 03:44:53
	(b) (4)	

US3252215

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Oct 2020 03:44:57
	(b) (4)	

US3252215

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	06 Oct 2020 03:44:57

US3252215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Oct 2020 18:56:48
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '12 Oct 2020'	Nancy Torrence (b) (4)	12 Oct 2020 18:56:48
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[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 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	12 Oct 2020 18:56:48
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'VISIT3'	System	12 Oct 2020 18:56:48

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '12 Oct 2020'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:11'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '12 Oct 2020 08:11'	System	12 Oct 2020 19:00:46

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '99.1' F	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '80'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'bpm'	System	12 Oct 2020 19:00:46

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '16'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'breaths/min'	System	12 Oct 2020 19:00:46

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '144'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	12 Oct 2020 19:00:46

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '80'	Nancy Torrence (b) (4)	12 Oct 2020 19:00:46
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'mmHg'	System	12 Oct 2020 19:00:46

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55

US3252215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55

US3252215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'No (N)'	Nancy Torrence (b) (4)	12 Oct 2020 19:01:23
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered empty.	Nancy Torrence (b) (4)	12 Oct 2020 19:01:23
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Oct 2020 19:03:47
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the accession ID in query response for tracking purpose once the sample is shipped.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the accession ID in query response for tracking purpose once the sample is shipped.' answered with '953942811800' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:55:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the accession ID in query response for tracking purpose once the sample is shipped.' (Site from DM).	Joanna Gurrola Mahoney	12 Mar 2021 15:22:27
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the tracking number and shipping date in query response for tracking purpose once the sample is shipped.' (Site from DM).	(b) (4)	12 Mar 2021 04:15:21
User signature succeeded.	(b) (4), (b) (6)	11 Mar 2021 06:38:45
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the tracking number and shipping date in query response for tracking purpose once the sample is shipped.' answered with '953942811800 24FEB2021' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 01:17:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response, however, please provide the tracking number and shipping date in query response for tracking purpose once the sample is shipped.' (Site from DM).	Joanna Gurrola Mahoney	04 Mar 2021 14:49:26
	(b) (4)	24 Feb 2021 10:51:07

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Req number is 1F623645867. Samples have not been shipped out yet but will be soon. Once they are shipped out AWB will be posted on portal for tracking of any samples' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:51:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '12 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	23 Feb 2021 15:55:12
	(b) (4), (b) (6)	07 Dec 2020 06:14:21
	Nancy Torrence (b) (4)	12 Oct 2020 19:03:47

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered '08:19'	Nancy Torrence (b) (4)	12 Oct 2020 19:03:47
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '12 Oct 2020 08:19'	System	12 Oct 2020 19:03:47

US3252215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:17:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Oct 2020 19:05:31
	(b) (4)	

US3252215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered '1'	System	12 Oct 2020 19:05:31

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 64'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-19T12:37:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f7e43c50-75e9-4ea2-8773-1fa6825680d2'	System	19 Oct 2020 17:41:28
User entered 'No (N)'	System	19 Oct 2020 17:41:28

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-19T12:38:05', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f7e43c50-75e9-4ea2-8773-1fa6825680d2'	System	19 Oct 2020 17:41:28
User entered 'No (N)'	System	19 Oct 2020 17:41:28

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-19T12:39:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f7e43c50-75e9-4ea2-8773-1fa6825680d2'	System	19 Oct 2020 17:41:28
User entered '19 Oct 2020 12:39:10'	System	19 Oct 2020 17:41:28

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 71'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-26T09:44:13', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fd5b94a7-82df-456a-9b16-752b03b535bf'	System	26 Oct 2020 14:46:01
User entered 'No (N)'	System	26 Oct 2020 14:46:01

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-26T09:44:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fd5b94a7-82df-456a-9b16-752b03b535bf'	System	26 Oct 2020 14:46:01
User entered 'No (N)'	System	26 Oct 2020 14:46:01

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-10-26T09:45:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'fd5b94a7-82df-456a-9b16-752b03b535bf'	System	26 Oct 2020 14:46:01
User entered '26 Oct 2020 09:45:58'	System	26 Oct 2020 14:46:01

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 78'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-02T16:27:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'd014b09f-f21d-4fa9-a934-5300e7a5a8cd'	System	02 Nov 2020 22:28:32
User entered 'No (N)'	System	02 Nov 2020 22:28:32

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-02T16:27:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'd014b09f-f21d-4fa9-a934-5300e7a5a8cd'	System	02 Nov 2020 22:28:32
User entered 'No (N)'	System	02 Nov 2020 22:28:32

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-02T16:28:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'd014b09f-f21d-4fa9-a934-5300e7a5a8cd'	System	02 Nov 2020 22:28:32
User entered '02 Nov 2020 16:28:30'	System	02 Nov 2020 22:28:32

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered 'Day 92'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-14T10:58:09', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '86e95bab-d185-4a16-82ab-9fb142f40227'	System	14 Nov 2020 16:58:42
User entered 'No (N)'	System	14 Nov 2020 16:58:42

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-14T10:58:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '86e95bab-d185-4a16-82ab-9fb142f40227'	System	14 Nov 2020 16:58:42
User entered 'No (N)'	System	14 Nov 2020 16:58:42

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-14T10:58:38', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '86e95bab-d185-4a16-82ab-9fb142f40227'	System	14 Nov 2020 16:58:42
User entered '14 Nov 2020 10:58:38'	System	14 Nov 2020 16:58:42

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 21:06:36

US3252215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:17:26
Data entry locked.	System	17 Aug 2020 21:06:36
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 21:06:36

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-11-19T09:50:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '983e46e0-08c2-4a29-a4b2-83673baa440a'	System	19 Nov 2020 15:51:13
User entered 'No (N)'	System	19 Nov 2020 15:51:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-11-19T09:50:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '983e46e0-08c2-4a29-a4b2-83673baa440a'	System	19 Nov 2020 15:51:13
User entered 'No (N)'	System	19 Nov 2020 15:51:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-19T09:51:08', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '983e46e0-08c2-4a29-a4b2-83673baa440a'	System	19 Nov 2020 15:51:13
User entered '19 Nov 2020 09:51:08'	System	19 Nov 2020 15:51:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-11-25T08:01:35', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7bcdff44-384e-4639-9395-8db259fa3764'	System	25 Nov 2020 14:02:34
User entered 'No (N)'	System	25 Nov 2020 14:02:34

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-11-25T08:01:57', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7bcdff44-384e-4639-9395-8db259fa3764'	System	25 Nov 2020 14:02:34
User entered 'No (N)'	System	25 Nov 2020 14:02:34

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-11-25T08:02:32', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '7bcdff44-384e-4639-9395-8db259fa3764'	System	25 Nov 2020 14:02:34
User entered '25 Nov 2020 08:02:32'	System	25 Nov 2020 14:02:34

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:22:12
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'data entered by the patient from the device. the site cannot make any changes.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:44:49
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 09:35:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-02T09:12:08', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered 'Yes (Y)'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-12-02T09:13:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered 'No (N)'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-02T09:17:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered 'No (N)'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-02T09:14:53', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered 'Yes (Y)'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-02T09:15:28', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-02T09:18:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '3b71d0ac-5d27-4325-8f1e-a6f342fd9238'	System	02 Dec 2020 15:18:50
User entered '02 Dec 2020 09:18:41'	System	02 Dec 2020 15:18:50

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-09T09:06:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '106b2f97-f4b7-452c-8d45-d6cd76a438ff'	System	09 Dec 2020 15:07:44
User entered 'No (N)'	System	09 Dec 2020 15:07:44

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-12-09T09:07:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '106b2f97-f4b7-452c-8d45-d6cd76a438ff'	System	09 Dec 2020 15:07:44
User entered 'No (N)'	System	09 Dec 2020 15:07:44

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-09T09:07:45', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '106b2f97-f4b7-452c-8d45-d6cd76a438ff'	System	09 Dec 2020 15:07:44
User entered '09 Dec 2020 09:07:45'	System	09 Dec 2020 15:07:44

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-16T09:09:43', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f83a460b-c6b6-49bb-9d3d-f5447e4115c4'	System	16 Dec 2020 15:13:20
User entered 'Yes (Y)'	System	16 Dec 2020 15:13:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-12-16T09:09:29', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f83a460b-c6b6-49bb-9d3d-f5447e4115c4'	System	16 Dec 2020 15:13:20
User entered 'No (N)'	System	16 Dec 2020 15:13:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-16T09:12:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f83a460b-c6b6-49bb-9d3d-f5447e4115c4'	System	16 Dec 2020 15:13:20
User entered 'No (N)'	System	16 Dec 2020 15:13:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-16T09:12:38', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f83a460b-c6b6-49bb-9d3d-f5447e4115c4'	System	16 Dec 2020 15:13:20
User entered 'No (N)'	System	16 Dec 2020 15:13:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-16T09:13:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'f83a460b-c6b6-49bb-9d3d-f5447e4115c4'	System	16 Dec 2020 15:13:20
User entered '16 Dec 2020 09:13:15'	System	16 Dec 2020 15:13:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-23T09:09:48', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8295dff2-b4f7-4611-a218-9bfed13c0c17'	System	23 Dec 2020 15:10:36
User entered 'No (N)'	System	23 Dec 2020 15:10:36

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-12-23T09:10:11', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8295dff2-b4f7-4611-a218-9bfed13c0c17'	System	23 Dec 2020 15:10:36
User entered 'No (N)'	System	23 Dec 2020 15:10:36

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-23T09:10:31', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '8295dff2-b4f7-4611-a218-9bfed13c0c17'	System	23 Dec 2020 15:10:36
User entered '23 Dec 2020 09:10:31'	System	23 Dec 2020 15:10:36

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2020-12-31T07:46:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15532a2e-7e70-460e-9fed-d545f8e49a62'	System	31 Dec 2020 13:48:27
User entered 'No (N)'	System	31 Dec 2020 13:48:27

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2020-12-31T07:47:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15532a2e-7e70-460e-9fed-d545f8e49a62'	System	31 Dec 2020 13:48:27
User entered 'No (N)'	System	31 Dec 2020 13:48:27

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2020-12-31T07:48:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15532a2e-7e70-460e-9fed-d545f8e49a62'	System	31 Dec 2020 13:48:27
User entered '31 Dec 2020 07:48:22'	System	31 Dec 2020 13:48:27

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-01-06T09:53:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62532d25-d9ec-428a-ac5f-2ffd730a8d96'	System	06 Jan 2021 15:53:40
User entered 'No (N)'	System	06 Jan 2021 15:53:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-01-06T09:53:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62532d25-d9ec-428a-ac5f-2ffd730a8d96'	System	06 Jan 2021 15:53:40
User entered 'No (N)'	System	06 Jan 2021 15:53:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-01-06T09:53:35', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '62532d25-d9ec-428a-ac5f-2ffd730a8d96'	System	06 Jan 2021 15:53:40
User entered '06 Jan 2021 09:53:35'	System	06 Jan 2021 15:53:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-01-13T09:43:21', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '239d77e8-4af8-40d0-995e-8970d4136a06'	System	13 Jan 2021 15:43:41
User entered 'No (N)'	System	13 Jan 2021 15:43:41

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-01-13T09:43:30', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '239d77e8-4af8-40d0-995e-8970d4136a06'	System	13 Jan 2021 15:43:41
User entered 'No (N)'	System	13 Jan 2021 15:43:41

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-01-13T09:43:40', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '239d77e8-4af8-40d0-995e-8970d4136a06'	System	13 Jan 2021 15:43:41
User entered '13 Jan 2021 09:43:40'	System	13 Jan 2021 15:43:41

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-01-20T13:57:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ba858350-37b2-45f3-b2f8-f35eeb79d7de'	System	20 Jan 2021 19:58:48
User entered 'No (N)'	System	20 Jan 2021 19:58:48

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-01-20T13:58:21', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ba858350-37b2-45f3-b2f8-f35eeb79d7de'	System	20 Jan 2021 19:58:48
User entered 'No (N)'	System	20 Jan 2021 19:58:48

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-01-20T13:58:44', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ba858350-37b2-45f3-b2f8-f35eeb79d7de'	System	20 Jan 2021 19:58:48
User entered '20 Jan 2021 13:58:44'	System	20 Jan 2021 19:58:48

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-01-27T08:14:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '35bbde7f-3e16-43e5-b466-b77e6f20998f'	System	27 Jan 2021 14:15:43
User entered 'No (N)'	System	27 Jan 2021 14:15:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-01-27T08:15:15', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '35bbde7f-3e16-43e5-b466-b77e6f20998f'	System	27 Jan 2021 14:15:43
User entered 'No (N)'	System	27 Jan 2021 14:15:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-01-27T08:15:42', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '35bbde7f-3e16-43e5-b466-b77e6f20998f' User entered '27 Jan 2021 08:15:42'	System	27 Jan 2021 14:15:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-02-03T06:39:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '599900a9-f478-42cf-bd0f-ce332261e9ab'	System	03 Feb 2021 12:40:31
User entered 'No (N)'	System	03 Feb 2021 12:40:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-02-03T06:40:00', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '599900a9-f478-42cf-bd0f-ce332261e9ab'	System	03 Feb 2021 12:40:31
User entered 'No (N)'	System	03 Feb 2021 12:40:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-03T06:40:22', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '599900a9-f478-42cf-bd0f-ce332261e9ab'	System	03 Feb 2021 12:40:31
User entered '03 Feb 2021 06:40:22'	System	03 Feb 2021 12:40:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-02-10T20:29:03', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '28637705-e0df-403b-971f-acfc59378171'	System	11 Feb 2021 02:34:20
User entered 'No (N)'	System	11 Feb 2021 02:34:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-02-10T20:29:17', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '28637705-e0df-403b-971f-acfc59378171'	System	11 Feb 2021 02:34:20
User entered 'No (N)'	System	11 Feb 2021 02:34:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-10T20:29:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '28637705-e0df-403b-971f-acfc59378171'	System	11 Feb 2021 02:34:20
User entered '10 Feb 2021 20:29:24'	System	11 Feb 2021 02:34:20

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-02-17T07:47:33', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15167489-7076-4182-b7cf-d0def4fbe3e6'	System	17 Feb 2021 13:48:00
User entered 'No (N)'	System	17 Feb 2021 13:48:00

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-02-17T07:47:41', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15167489-7076-4182-b7cf-d0def4fbe3e6'	System	17 Feb 2021 13:48:00
User entered 'No (N)'	System	17 Feb 2021 13:48:00

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-17T07:47:57', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '15167489-7076-4182-b7cf-d0def4fbe3e6'	System	17 Feb 2021 13:48:00
User entered '17 Feb 2021 07:47:57'	System	17 Feb 2021 13:48:00

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-02-27T10:00:07', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b122c0fe-3fcd-4554-91aa-3199aa0d3e61'	System	27 Feb 2021 16:00:32
User entered 'No (N)'	System	27 Feb 2021 16:00:32

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-02-27T10:00:19', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b122c0fe-3fcd-4554-91aa-3199aa0d3e61'	System	27 Feb 2021 16:00:32
User entered 'No (N)'	System	27 Feb 2021 16:00:32

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-27T10:00:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'b122c0fe-3fcd-4554-91aa-3199aa0d3e61'	System	27 Feb 2021 16:00:32
User entered '27 Feb 2021 10:00:27'	System	27 Feb 2021 16:00:32

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-03-06T09:27:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '916f265b-2e40-43bc-a4e9-3896ab8d8a7c'	System	06 Mar 2021 15:28:18
User entered 'No (N)'	System	06 Mar 2021 15:28:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-03-06T09:28:04', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '916f265b-2e40-43bc-a4e9-3896ab8d8a7c'	System	06 Mar 2021 15:28:18
User entered 'No (N)'	System	06 Mar 2021 15:28:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-03-06T09:28:13', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '916f265b-2e40-43bc-a4e9-3896ab8d8a7c'	System	06 Mar 2021 15:28:18
User entered '06 Mar 2021 09:28:13'	System	06 Mar 2021 15:28:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-03-10T07:29:34', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0e29aa46-6e10-48cc-a110-0424a3a03b2d'	System	10 Mar 2021 13:30:18
User entered 'No (N)'	System	10 Mar 2021 13:30:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-03-10T07:29:53', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0e29aa46-6e10-48cc-a110-0424a3a03b2d'	System	10 Mar 2021 13:30:18
User entered 'No (N)'	System	10 Mar 2021 13:30:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-03-10T07:30:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0e29aa46-6e10-48cc-a110-0424a3a03b2d'	System	10 Mar 2021 13:30:18
User entered '10 Mar 2021 07:30:12'	System	10 Mar 2021 13:30:18

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-03-17T09:10:44', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1260aa36-e1db-43f5-936d-d6f332e6ca27'	System	17 Mar 2021 14:11:28
User entered 'No (N)'	System	17 Mar 2021 14:11:28

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-03-17T09:10:55', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1260aa36-e1db-43f5-936d-d6f332e6ca27'	System	17 Mar 2021 14:11:28
User entered 'No (N)'	System	17 Mar 2021 14:11:28

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-03-17T09:11:25', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1260aa36-e1db-43f5-936d-d6f332e6ca27'	System	17 Mar 2021 14:11:28
User entered '17 Mar 2021 09:11:25'	System	17 Mar 2021 14:11:28

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-03-24T10:27:24', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ad0df591-6b29-46bf-986b-0b550c6a3749'	System	24 Mar 2021 15:28:13
User entered 'No (N)'	System	24 Mar 2021 15:28:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-03-24T10:27:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ad0df591-6b29-46bf-986b-0b550c6a3749'	System	24 Mar 2021 15:28:13
User entered 'No (N)'	System	24 Mar 2021 15:28:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-03-24T10:28:10', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'ad0df591-6b29-46bf-986b-0b550c6a3749'	System	24 Mar 2021 15:28:13
User entered '24 Mar 2021 10:28:10'	System	24 Mar 2021 15:28:13

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-03-31T11:30:18', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1ebc2c6d-e1ad-425b-a281-cbcce9ce2625'	System	31 Mar 2021 16:30:43
User entered 'No (N)'	System	31 Mar 2021 16:30:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-03-31T11:30:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1ebc2c6d-e1ad-425b-a281-cbcce9ce2625'	System	31 Mar 2021 16:30:43
User entered 'No (N)'	System	31 Mar 2021 16:30:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-03-31T11:30:36', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '1ebc2c6d-e1ad-425b-a281-cbcce9ce2625'	System	31 Mar 2021 16:30:43
User entered '31 Mar 2021 11:30:36'	System	31 Mar 2021 16:30:43

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-04-07T09:46:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '5983ed20-6689-4f54-8559-4088538af294'	System	07 Apr 2021 14:47:31
User entered 'No (N)'	System	07 Apr 2021 14:47:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-04-07T09:47:14', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '5983ed20-6689-4f54-8559-4088538af294'	System	07 Apr 2021 14:47:31
User entered 'No (N)'	System	07 Apr 2021 14:47:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-04-07T09:47:27', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '5983ed20-6689-4f54-8559-4088538af294'	System	07 Apr 2021 14:47:31
User entered '07 Apr 2021 09:47:27'	System	07 Apr 2021 14:47:31

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-04-14T15:18:38', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aef29217-1742-4829-b53d-c545c09b8c7e'	System	14 Apr 2021 20:19:01
User entered 'No (N)'	System	14 Apr 2021 20:19:01

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-04-14T15:18:52', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aef29217-1742-4829-b53d-c545c09b8c7e'	System	14 Apr 2021 20:19:01
User entered 'No (N)'	System	14 Apr 2021 20:19:01

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-04-14T15:18:59', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'aef29217-1742-4829-b53d-c545c09b8c7e'	System	14 Apr 2021 20:19:01
User entered '14 Apr 2021 15:18:59'	System	14 Apr 2021 20:19:01

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-04-23T17:01:26', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '397eb2c6-d2fc-4d5e-bb98-c7701c87b5dd'	System	23 Apr 2021 22:06:12
User entered 'No (N)'	System	23 Apr 2021 22:06:12

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-04-23T17:01:37', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '397eb2c6-d2fc-4d5e-bb98-c7701c87b5dd'	System	23 Apr 2021 22:06:12
User entered 'No (N)'	System	23 Apr 2021 22:06:12

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-04-23T17:01:53', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '397eb2c6-d2fc-4d5e-bb98-c7701c87b5dd'	System	23 Apr 2021 22:06:12
User entered '23 Apr 2021 17:01:53'	System	23 Apr 2021 22:06:12

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[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 (c125213ab60e92b3)', Time: '2021-04-28T09:49:05', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'df398e54-732b-4bb9-a239-0a93570f3d3a'	System	28 Apr 2021 21:58:40
User entered 'No (N)'	System	28 Apr 2021 21:58:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

Have you been exposed to someone with 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 (c125213ab60e92b3)', Time: '2021-04-28T09:49:23', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'df398e54-732b-4bb9-a239-0a93570f3d3a'	System	28 Apr 2021 21:58:40
User entered 'No (N)'	System	28 Apr 2021 21:58:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-04-28T09:49:58', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: 'df398e54-732b-4bb9-a239-0a93570f3d3a'	System	28 Apr 2021 21:58:40
User entered '28 Apr 2021 09:49:58'	System	28 Apr 2021 21:58:40

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:36:54

US3252215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:36:54
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:36:54

US3252215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:44

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-27T10:00:54', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0172fb44-2281-42b8-901e-5d6337370014'	System	27 Feb 2021 16:01:19
User entered 'No (N)'	System	27 Feb 2021 16:01:19

US3252215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c125213ab60e92b3)', Time: '2021-02-27T10:01:12', User OID: 'PatientReportedOutcome (US3252215)', ODM File OID: '0172fb44-2281-42b8-901e-5d6337370014'	System	27 Feb 2021 16:01:19
User entered '27 Feb 2021 10:01:12'	System	27 Feb 2021 16:01:19

US3252215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	10 Nov 2020 03:30:02
	(b) (4)	

US3252215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '9 Nov 2020'	Nancy Torrence (b) (4)	10 Nov 2020 03:30:02
	(b) (4)	

US3252215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	10 Nov 2020 03:30:02
	(b) (4)	

US3252215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Nancy Torrence (b) (4)	10 Nov 2020 03:30:02
	(b) (4)	

US3252215

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	10 Nov 2020 03:30:08
	(b) (4)	

US3252215

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:15:55
User entered 'I'	System	10 Nov 2020 03:30:08

US3252215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Dec 2020 02:26:55
	(b) (4)	

US3252215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '12 Dec 2020'	Shannon Moyer (b) (4)	14 Dec 2020 02:26:55
	(b) (4)	

US3252215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	14 Dec 2020 02:26:55
	(b) (4)	

US3252215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	14 Dec 2020 02:26:55
	(b) (4)	

US3252215

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Dec 2020 02:26:59
	(b) (4)	

US3252215

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'I'	System	14 Dec 2020 02:26:59

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:04:47
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 07:50:28
User entered 'No (N)' reason for change: Data Entry Error		29 Mar 2021 07:50:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 05:32:53

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:04:47
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User entered '14 Jan 2021' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User closed query 'Visits Safety Call Day 119 and Safety Call Day 149 are both dated 12DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:55:48
Query 'Visits Safety Call Day 119 and Safety Call Day 149 are both dated 12DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:50:41
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 07:50:28
User entered empty; reason for change Data Entry Error		29 Mar 2021 07:50:28
User opened query 'Visits Safety Call Day 119 and Safety Call Day 149 are both dated 12DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM).		26 Mar 2021 11:10:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
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 10:31:16

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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 is' (Site from System).	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 05:33:11
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	05 Feb 2021 05:32:53
User entered '12 Dec 2020'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 05:32:53

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:04:47
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	07 Apr 2021 20:11:08
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 07:50:28
User entered empty; reason for change Data Entry Error		29 Mar 2021 07:50:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 05:32:53

US3252215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:04:47
Signature has been broken.	Joanna Gurrola Mahoney	07 Apr 2021 20:11:08
	(b) (4)	
User entered 'patient was contacted for safety call but did not return call, call was therefore missed.'	Joanna Gurrola Mahoney	07 Apr 2021 20:11:08
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 07:50:28
User entered empty; reason for change Data Entry Error		29 Mar 2021 07:50:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'left voice mail'	Joanna Gurrola Mahoney	05 Feb 2021 05:32:53
	(b) (4)	

US3252215

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 05:32:56

US3252215

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'I'	System	05 Feb 2021 05:32:56

US3252215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 08:33:21

US3252215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 11:13:30
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Due to inclement weather, patient communication was not possible.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 03:09:06
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Mar 2021 08:33:21
User entered '17 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 08:33:21

US3252215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 08:33:21

US3252215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 08:33:21

US3252215

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 08:33:27

US3252215

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'I'	System	04 Mar 2021 08:33:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 06:36:20

US3252215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 06:36:20

US3252215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[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 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Mar 2021 06:36:20

US3252215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'VISIT4'	System	05 Mar 2021 06:36:20

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '4 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '07:45'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered '4 Mar 2021 07:45'	System	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '97.6' F	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '76'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'bpm'	System	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'breaths/min'	System	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '135'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'mmHg'	System	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '66'	(b) (4), (b) (6)	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'mmHg'	System	30 Mar 2021 19:18:27

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57

US3252215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57

US3252215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 06:36:35

US3252215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 06:36:35

US3252215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 06:36:40

US3252215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 06:36:40

US3252215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 06:36:40

US3252215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered empty.	System	05 Mar 2021 06:36:40

US3252215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 06:36:44

US3252215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:20:57
User entered 'I'	System	05 Mar 2021 06:36:44

US3252215

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

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:27:46
	(b) (4)	

US3252215

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

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:27:46
	(b) (4)	

US3252215

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

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	08 Jan 2021 03:27:46
	(b) (4)	

US3252215

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

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 03:27:46

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:32:23
	(b) (4)	

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:24:51

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:32:23
	(b) (4)	

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:54:26
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:24:51

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:32:23
	(b) (4)	

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4)	08 Jan 2021 03:32:23
	(b) (4)	

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:29:53
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 03:32:23

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:29:53
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 03:32:23

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:32:23
	(b) (4)	

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '1'	System	08 Jan 2021 03:32:23

US3252215

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'I'	System	08 Jan 2021 03:32:23

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '141' cm	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '79.5' kg	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '39.98793'	System	08 Jan 2021 03:34:02
DataPoint set to visible.	System	08 Jan 2021 03:32:23

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '141' cm	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '79.5' kg	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '39.98793'	System	08 Jan 2021 03:34:02
DataPoint set to visible.	System	08 Jan 2021 03:32:23

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '07:37'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '7 Jan 2021 07:37'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '98.6' F	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '86'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'bpm'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '15'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'breaths/min'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '153'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '82'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '141' cm	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '79.5' kg	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '39.98793'	System	08 Jan 2021 03:34:02
DataPoint set to visible.	System	08 Jan 2021 03:32:23

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:57'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '7 Jan 2021 08:57'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '98.0' F	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '80'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'bpm'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '14'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'breaths/min'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '136'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '78'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:02
	(b) (4)	

US3252215

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	08 Jan 2021 03:34:02

US3252215

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:15
	(b) (4)	

US3252215

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:15
	(b) (4)	

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	08 Jan 2021 03:34:39
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	08 Jan 2021 03:34:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	08 Jan 2021 03:34:39
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	08 Jan 2021 03:34:32
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:32

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		08 Jan 2021 03:34:39
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	08 Jan 2021 03:34:32
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 03:34:32

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	08 Jan 2021 03:34:32
	(b) (4)	

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mRNA-1273'	System	08 Jan 2021 03:34:39
User entered empty.	System	08 Jan 2021 03:34:32
DataPoint set to visible.	System	08 Jan 2021 03:32:23

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:32
	(b) (4)	

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:23'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:32
	(b) (4)	

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '7 Jan 2021 08:23'	System	08 Jan 2021 03:34:32

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Left Arm (LEFT ARM)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:32
	(b) (4)	

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'ONCE'	System	08 Jan 2021 03:34:39
User entered empty.	System	08 Jan 2021 03:34:32

US3252215

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 03:34:39
User entered empty.	System	08 Jan 2021 03:34:32

US3252215

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:52
	(b) (4)	

US3252215

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:52
	(b) (4)	

US3252215

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:04'	Shannon Moyer (b) (4)	08 Jan 2021 03:34:52
	(b) (4)	

US3252215

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '7 Jan 2021 08:04'	System	08 Jan 2021 03:34:52

US3252215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:35:03
	(b) (4)	

US3252215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 03:35:03
	(b) (4)	

US3252215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:03'	Shannon Moyer (b) (4)	08 Jan 2021 03:35:03
	(b) (4)	

US3252215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '7 Jan 2021 08:03'	System	08 Jan 2021 03:35:03

US3252215

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

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 03:35:08
	(b) (4)	

US3252215

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

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '1'	System	08 Jan 2021 03:35:08

US3252215

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:03

US3252215

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 15:15:07
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'subject visit is out of window period.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 04:07:55
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 01:09:13
User entered '26 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:03

US3252215

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:03

US3252215

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:03

US3252215

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:08

US3252215

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'I'	System	05 Feb 2021 03:43:08

US3252215

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '1'	System	05 Feb 2021 03:43:08
DataPoint set to visible.	System	05 Feb 2021 03:43:08

US3252215

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:38

US3252215

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Feb 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:38

US3252215

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:43:38

US3252215

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'OLD29'	System	05 Feb 2021 03:43:38

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User accepted default value 'Pre-Dose (PREDOSE)'	Joanna Gurrola Mahoney	05 Feb 2021 03:45:11
	(b) (4)	

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Feb 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '07:21'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '4 Feb 2021 07:21'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '97.8' F	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (Oral)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '80'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'bpm'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '16'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'breaths/min'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '148'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '89'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User accepted default value 'Post-Dose (POSTDOSE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Feb 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:45'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '4 Feb 2021 08:45'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '97.8' F	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (Oral)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '79'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'bpm'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '16'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'breaths/min'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '128'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '78'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Feb 2021 03:45:11

US3252215

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:18

US3252215

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:18

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mRNA-1273'	System	05 Feb 2021 03:45:44
DataPoint set to visible.	System	05 Feb 2021 03:43:08

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Feb 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '08:13'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '4 Feb 2021 08:13'	System	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:44:06
User entered 'ONCE'	System	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 03:45:44

US3252215

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:45:49

US3252215

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'I'	System	05 Feb 2021 03:45:49

US3252215

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 08:34:16

US3252215

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '12 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 08:34:16

US3252215

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 08:34:16

US3252215

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 08:34:16

US3252215

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 08:34:25

US3252215

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'I'	System	04 Mar 2021 08:34:25

US3252215

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 06:13:54

US3252215

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 06:13:54

US3252215

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Mar 2021 06:13:54

US3252215

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'OLD57'	System	05 Mar 2021 06:13:54

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '07:45'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '4 Mar 2021 07:45'	System	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '97.6' F	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '76'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'bpm'	System	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '16'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'breaths/min'	System	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '135'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '66'	(b) (4), (b) (6)	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered 'mmHg'	System	05 Mar 2021 06:14:45

US3252215

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 06:14:55

US3252215

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 06:14:55

US3252215

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 06:15:10

US3252215

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '4 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 06:15:10

US3252215

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '07:49'	(b) (4), (b) (6)	05 Mar 2021 06:15:10

US3252215

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:14:03
User entered '4 Mar 2021 07:49'	System	05 Mar 2021 06:15:10

US3252215

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:11:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:49:02
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:18
Signature has been broken.	Joanna Gurrola Mahoney	15 Apr 2021 14:28:44
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney	15 Apr 2021 14:28:44
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:32:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:04:00
Un-reviewed for Safety.		15 Apr 2021 20:03:55
Reviewed for Safety.		15 Apr 2021 19:15:59
User entered	System	15 Apr 2021 19:15:55
'USA-US108-2021-mRNA-1273-P301000018'		
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 19:15:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 May 2021 23:05:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 May 2021 23:05:22
Data point term sent to Coder	System	03 May 2021 21:53:11
Coding entries removed.	(b) (4), (b) (6)	03 May 2021 21:52:51
User entered 'Worsening PERIPHERAL ARTERY DISEASE' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 21:52:51
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 14:36:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 14:36:11
Data point term sent to Coder	System	15 Apr 2021 14:34:34
User entered 'peripheral artery disease'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	03 May 2021 21:52:51
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	03 May 2021 21:52:51
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 21:52:51
User closed query 'PV Query: The reported start date for the SAE is prior to subject enrollment. If this SAE is considered a worsening of an existing condition, please update the start date to the date it worsened and update the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:17:22
Query 'PV Query: The reported start date for the SAE is prior to subject enrollment. If this SAE is considered a worsening of an existing condition, please update the start date to the date it worsened and update the event term accordingly.' answered with 'The Subject had peripheral artery disease which is a chronic problem. The subject had an elective procedure done to remove the plaque build up. Since the subject was hospitalized over night for observation this had to be documented as an SAE' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:59:23
User opened query 'PV Query: The reported start date for the SAE is prior to subject enrollment. If this SAE is considered a worsening of an existing condition, please update the start date to the date it worsened and update the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:05:31
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	20 Apr 2021 03:21:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		20 Apr 2021 03:21:53
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		20 Apr 2021 03:21:53
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		20 Apr 2021 03:21:53
User entered '01 Jan 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 03:21:53
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Apr 2021 14:33:45
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		15 Apr 2021 14:33:45
User entered '01 Jan 0000'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
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	16 Apr 2021 04:59:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 04:59:34
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 14:33:45
User entered '00:00'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 04:59:34
User entered '01 Jan 0000 00:00'	System	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '23 Mar 2021'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 04:59:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:17:28
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)	01 May 2021 07:01:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' answered with 'no test was done from what the subject told us.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:59:54
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 'admission and discharge date is added' (Site from System).	(b) (4), (b) (6)	30 Apr 2021 08:15:58
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.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:09:04
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 14:33:45
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User closed query 'PV Query: Please confirm the reported hospital admission and discharge dates from the subject safety call and add them to the EDC.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:13:55
Query 'PV Query: Please confirm the reported hospital admission and discharge dates from the subject safety call and add them to the EDC.' answered with 'Has been updated' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 02:55:52
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 02:52:37
User opened query 'PV Query: Please confirm the reported hospital admission and discharge dates from the subject safety call and add them to the EDC.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:06:43
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 02:52:37
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'None (NONE)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '1'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered '1'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:35
User closed query 'PV Query: It was reported that the subject had a history of peripheral artery disease. Please add this to the subject's medical history (prior to onset of study) to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:18:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:17:36
Query 'PV Query: It was reported that the subject had a history of peripheral artery disease. Please add this to the subject's medical history (prior to onset of study) to medical history eCRF.' answered with 'This was updated to source still pending medical records from the subject.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:13:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'we are still pending medical records' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:00:19
User opened query 'PV Query: It was reported that the subject had a history of peripheral artery disease. Please add this to the subject's medical history (prior to onset of study) to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:08:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported on his safety call he recently had a scheduled procedure done on the 23rd of MAR 2021. Subject had a history of peripheral artery disease and recently had a scheduled femoral endarterectomy done on the 23rd of MAR 2021. He was admitted for over night observation and was discharged on the morning of the 24th of MAR. Subject was prescribed Xarelto 2.5 mg by mouth twice daily for prophylaxis post procedure. Subject is currently doing well as per subject.'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:33:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 14:33:45

US3252215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 14:33:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:11:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:49:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:34:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:54:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:54:18
Data point term sent to Coder	System	18 Aug 2020 19:40:58
User entered 'ALLOPURINOL'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:40:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 19:00:57
Query 'Per MM, Please revise the indication ' answered with 'Contacted patient, states he is on this medication for type II diabetes' (Site from DM).	Uche Ehiemua (b) (4)	05 Oct 2020 13:51:52
User opened query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:16:50
User entered 'TYPE 2 DIABETES'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '100'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:19:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:47:35
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:40:37
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:40:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:40:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:40:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:40:37

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: GLIBENCLAMIDE;METFORMIN, PRODUCTSYNONYM: GLUCOVANCE [GLIBENCLAMIDE;METFORMIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 00:43:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 00:43:15
Data point term sent to Coder	System	18 Aug 2020 19:41:59
User entered 'GLUCOVANCE'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Type 2 diabetes'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Per CDM: Response noted; however, according to CCGs, please enter the dose for the medication taken. If dose is unknown, enter 'UNK'. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:01:15
Query 'Per CDM: Response noted; however, according to CCGs, please enter the dose for the medication taken. If dose is unknown, enter 'UNK'. ' answered with 'dosage updated' (Site from DM).	Uche Ehiemua (b) (4)	05 Oct 2020 13:49:34
User entered '5/500' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 13:49:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:03:09
User opened query 'Per CDM: Response noted; however, according to CCGs, please enter the dose for the medication taken. If dose is unknown, enter 'UNK'. ' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 13:03:07
Query 'Data is required. Please complete.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4)	18 Aug 2020 19:47:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 19:41:21
	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'twice daily (BID)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:20:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:47:30
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:41:21
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:41:21
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 19:41:21

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:41:21

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:41:21

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: LINAGLIPTIN, PRODUCTSYNONYM: TRADJENTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:28:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:28:24
Data point term sent to Coder	System	18 Aug 2020 19:43:02
User entered 'TRADJENTA'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'TYPE 2 DIABETES'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '5'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:21:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:47:18
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:42:02
User entered 'UN UNK 2017'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:02
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:42:02

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:42:02

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:42:02

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:28:25
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 Aug 2020 23:28:25
Data point term sent to Coder	System	18 Aug 2020 19:43:04
User entered 'LISINOPRIL'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:42:43

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'HYPERTENSION'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '40'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:21:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:47:13
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:42:43
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:42:43
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:42:43

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:42:43

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:42:43

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:28:26
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 Aug 2020 23:28:26
Data point term sent to Coder	System	18 Aug 2020 19:44:07
User entered 'ATENOLOL'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:43:29

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'HYPERTENSION'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '100'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:22:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:47:08
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:43:29
User entered 'UN UNK 2010'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:43:29
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:43:29

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:43:29

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:43:29

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:53:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:53:21
Data point term sent to Coder	System	01 Oct 2020 13:51:56
Coding entries removed.	Xavier Morales (b) (4)	01 Oct 2020 13:51:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 21:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 21:44:42
Data point term sent to Coder	System	29 Sep 2020 21:44:28
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 21:44:14
User entered 'ADVAIR' reason for change: Data Entry Error		29 Sep 2020 21:44:14

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:34:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:34:07
Data point term sent to Coder	System	18 Aug 2020 19:47:15
User entered 'Adviar'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Asthma'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:30:55
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' ' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4)	01 Oct 2020 13:52:07
User entered '250/50' reason for change: Data Entry Error	Xavier Morales (b) (4)	01 Oct 2020 13:51:53
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 11:29:45
User entered '500'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 06:11:14
User entered 'Other (OTHER)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	10 Nov 2020 06:11:14
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 06:11:07
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:30:58
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4)	01 Oct 2020 13:52:14
User entered 'ug (ug)' reason for change: Data Entry Error	Xavier Morales (b) (4)	01 Oct 2020 13:51:53
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 11:30:37
User entered 'mg (mg)'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'mcg' reason for change: Data Entry Error	Nancy Torrence (b) (4)	10 Nov 2020 06:11:07
User entered empty.	(b) (4)	
	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'twice daily (BID)'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Per MM, Please revise the route of administration ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:35:33
Query 'Per MM, Please revise the route of administration ' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	01 Oct 2020 13:52:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	01 Oct 2020 13:51:53
User opened query 'Per MM, Please revise the route of administration ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:24:43
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 08:23:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:58
answered with 'Per Source, correct as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 19:46:20
User entered 'UN UNK 2015'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Aug 2020 19:46:20
	(b) (4)	

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:46:20

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 06:13:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 06:12:51
Coding entries removed.	Nancy Torrence (b) (4)	10 Nov 2020 06:11:56
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:18:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:18:44
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 15:27:10
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'INFLUENZA Prophylaxis' reason for change: Data Entry Error	Nancy Torrence (b) (4)	10 Nov 2020 06:11:56
User entered 'Influenza'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User closed query 'Per CDM: Dose per administration should be "UNK" if data is Unknown. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:48:35
Query 'Per CDM: Dose per administration should be "UNK" if data is Unknown. Please update accordingly.' answered with 'Dose updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	19 Nov 2020 20:42:36
User entered '180' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	19 Nov 2020 20:42:13
User opened query 'Per CDM: Dose per administration should be "UNK" if data is Unknown. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:39:46
User entered 'Unknown'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'IU (IU)' reason for change: Data Entry	Joanna Gurrola Mahoney	19 Nov 2020 20:42:13
Error	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty; reason for change Data Entry	Joanna Gurrola Mahoney	19 Nov 2020 20:42:13
Error	(b) (4)	
User entered 'Unknown'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '28 Sep 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4)	10 Nov 2020 06:11:56
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered '28 Sep 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4)	10 Nov 2020 06:11:56
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User entered empty.	System	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User entered empty.	System	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:42
User entered empty.	System	08 Oct 2020 15:27:05

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 14:39:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 14:39:30
Data point term sent to Coder	System	15 Apr 2021 14:37:37
User entered 'xarelto'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'post femoral endarterectomy'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '2.5'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'twice daily (BID)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '23 Mar 2021'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '0'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 05:08:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 05:08:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 05:08:02
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 14:36:44
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 14:36:44

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:11:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:24:50
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 12:53:30
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Aug 2020 19:33:41
	(b) (4)	

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '23 Mar 2021'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:37:55

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'femoral endarterectomy'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:37:55

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered 'Adverse Event (AE)'	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:37:55

US3252215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	15 Apr 2021 14:37:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '15/Apr/2021 15:16'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:44

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 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'l'	spallan1)	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '15/Apr/2021 16:05'	System	15 Apr 2021 20:05:57

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:44

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 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 11:33:44
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 20:05:57

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '16/Apr/2021 13:24'	System	16 Apr 2021 20:24:53

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:44

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 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 11:33:44
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 20:24:53

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:11:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
User entered '20/Apr/2021 07:33'	System	20 Apr 2021 11:33:57

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:11:44

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 18:51:20
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 11:33:57

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:28
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:05:12
Un-reviewed for Safety.		15 Apr 2021 20:05:08
Reviewed for Safety.		15 Apr 2021 20:05:02
Un-reviewed for Safety.		15 Apr 2021 20:04:58
Reviewed for Safety.		15 Apr 2021 19:16:37
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:26
Un-reviewed for Safety.		15 Apr 2021 19:16:21
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'USA-US108-2021-MRNA-1273-P301000018'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Yes (Y)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'No (N)'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Joel'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Solis'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered '5201 N. 10th Street'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'Mcallen'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'TX'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 19:16:41
Un-reviewed for Safety.		15 Apr 2021 19:16:33
Reviewed for Safety.		15 Apr 2021 19:16:16
User entered 'carmpa'	System	15 Apr 2021 19:15:55

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 20:05:32
Un-reviewed for Safety.		15 Apr 2021 20:05:22
Reviewed for Safety.		15 Apr 2021 20:04:36
User entered 'US'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 15:17:19
User entered '4'	System	20 Apr 2021 11:33:57
User entered '3'	System	16 Apr 2021 20:24:53
User entered '2'	System	15 Apr 2021 20:05:57
User entered '1'	System	15 Apr 2021 19:16:52

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:11:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:35:45
User entered '27/Apr/2021 08:17'	System	27 Apr 2021 15:17:19

US3252215

Folder: SAE USA-US108-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:11:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:35:45
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 15:17:19