

US3992037 (Prod: University of Chicago)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:41:11

All time stamps listed in this document are displayed in GMT

US3992037

Form: Participant Creation

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

[Participant ID](#)

US3992037

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

US3992037

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: Screening

Form: Demographics

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	23
Age Units	YEARS
Age (Derived)	23
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

US3992037

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3992037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3992037

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Were any significant conditions reported?

Yes ☐

No ☒

US3992037

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:00
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	125 lb
BMI (<i>xxx.x</i>)	20.84458 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)	

US3992037

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3992037

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3992037

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

What was the date of randomization? (dd MMM yyyy) 26 SEP 2020

What was the participant's randomization number? 115702

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 ☒

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Height	ND - Not Done
Weight	ND - Not Done

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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)	26 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:00
Temperature (xxx.x)	35.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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)	26 SEP 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:17
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 SEP 2020

What was the treatment time? (00:00-23:59) 11:47 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 11:47

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

US3992037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

11:01 (24 HR)

Collection date and time (derived)

26 SEP 2020 11:01

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:03	26 SEP 2020 11:03
Nasopharyngeal Swab 2	Yes	11:03	26 SEP 2020 11:03

US3992037

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:20

PC Open Date & Time

26 SEP 2020 12:07

PC Close Date & Time

26 SEP 2020 14:37

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °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	26 SEP 2020 23:25
PC Open Date & Time	26 SEP 2020 15:32
PC Close Date & Time	27 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

28 SEP 2020 00:34

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

97.2 °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

29 SEP 2020 01:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

98.3 °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

30 SEP 2020 01:47

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 00:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 01:07

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

26 SEP 2020 12:20

PC Open Date & Time

26 SEP 2020 12:07

PC Close Date & Time

26 SEP 2020 14:37

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 23:22

PC Open Date & Time

26 SEP 2020 15:32

PC Close Date & Time

27 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

28 SEP 2020 00:32

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

29 SEP 2020 01:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

30 SEP 2020 01:47

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

30 SEP 2020 23:59

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

02 OCT 2020 01:07

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 12:21
PC Open Date & Time	26 SEP 2020 12:07
PC Close Date & Time	26 SEP 2020 14:37

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 23:21
PC Open Date & Time	26 SEP 2020 15:32
PC Close Date & Time	27 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

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 ☒

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 00:32
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

43 of 2020

EAB) (1725)

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 01:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

45 of 2020

EAB) (1725)

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 01:48
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

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 ☒

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 23:59
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

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 ☒

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 01:07
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3992037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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)	30 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:28
Temperature (xxx.x)	35.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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)	30 OCT 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:50
Temperature (xxx.x)	35.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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) 30 OCT 2020

What was the treatment time? (00:00-23:59) 9:20 (24 HR)

Treatment Date and Time (derived) 30 OCT 2020 9:20

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

US3992037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

08:42 (24 HR)

Collection date and time (derived)

30 OCT 2020 08:42

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Collection date (dd MMM yyyy)			30 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:45	30 OCT 2020 08:45
Nasopharyngeal Swab 2	Yes	08:45	30 OCT 2020 08:45

US3992037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 09:52

PC Open Date & Time

30 OCT 2020 09:40

PC Close Date & Time

30 OCT 2020 12:10

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 OCT 2020 13:05

PC Close Date & Time

31 OCT 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 01:03

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 16:30

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 23:51

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 09:52

PC Open Date & Time

30 OCT 2020 09:40

PC Close Date & Time

30 OCT 2020 12:10

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 OCT 2020 13:05

PC Close Date & Time

31 OCT 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

31 OCT 2020 23:57

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

03 NOV 2020 14:49

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 23:51

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 09:52
PC Open Date & Time	30 OCT 2020 09:40
PC Close Date & Time	30 OCT 2020 12:10

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

30 OCT 2020 13:05

PC Close Date & Time

31 OCT 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

87 of 2020

EAB) (1725)

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 23:58
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

Yes ☐

PC Time stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

Yes ☐

PC Time stamp

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

93 of 2020

EAB) (1725)

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 14:50
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

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 ☒

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 23:52
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

Yes ☐

PC Time stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3992037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	VISIT3

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:42:57

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 JAN 2021
Time of assessment (00:00-23:59)	13:21 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 13:21
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 JAN 2021

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

US3992037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 JAN 2021

Collection time (00:00-23:59)

13:25 (24 HR)

Collection date and time (derived)

06 JAN 2021 13:25

US3992037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission	
-----------------------------	--

Patient Cloud Open Date & Time	23 NOV 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	27 NOV 2020 23:59
---	-------------------

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 DEC 2020 15:56:21
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 12:00:14

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 21:36:54

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission	
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you 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	30 DEC 2020 12:01:36
Patient Cloud Open Date & Time	28 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
117 of 2020	

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 <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	04 JAN 2021 00:01:32
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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	13 JAN 2021 12:14:12
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

20 JAN 2021 12:00:19

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 16:55:13

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

03 FEB 2021 12:02:02

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

10 FEB 2021 12:00:35

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

17 FEB 2021 16:32:50

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

24 FEB 2021 17:00:18

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

03 MAR 2021 20:33:47

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

11 MAR 2021 20:18:57

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 16:34:43

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 16:17:44

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

01 APR 2021 17:59:27

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

07 APR 2021 15:25:11

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

16 APR 2021 12:05:12

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 17:59:21

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

28 APR 2021 13:19:52

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 222

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 229

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 271

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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°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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

Patient Cloud Open Date & Time	13 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	17 DEC 2021 23:59
---	-------------------

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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="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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 656

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2022 23:59
---	-------------------

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 <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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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="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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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="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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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="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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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"/>

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

DAY 796

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

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

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

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

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

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

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2022 23:59

US3992037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:41:11

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		03 MAR 2021 20:33:41

US3992037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:41:22

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:41:22

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 15:06:34

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 15:06:34

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 15:07:08

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 15:07:08

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3992037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 15:07:08

Generated On: 10 Jun 2021 10:41:11

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.

US3992037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 15:07:08

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 APR 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

27 APR 2021 14:25

US3992037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 15:07:08

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3992037

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:41:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3992037

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

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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

Visit date (dd MMM yyyy)	06 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
------------	---------------

US3992037

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 20:02:08

Generated On: 10 Jun 2021 10:41:11

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 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>)	06 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

US3992037

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Height	165.1 cm
Weight	56.7 kg
BMI (xxx.x)	20.80123

US3992037

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Height	165.1 cm
Weight	56.7 kg
BMI (xxx.x)	20.80123
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)	06 JAN 2021
Time of assessment (00:00-23:59)	13:21 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 13:21
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Height	165.1 cm
Weight	56.7 kg
BMI (xxx.x)	20.80123
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)	06 JAN 2021
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 14:20
Temperature (xxx.x)	37.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

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

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 JAN 2021

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

US3992037

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

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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) 06 JAN 2021

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 06 JAN 2021 13:50

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

US3992037

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 JAN 2021

Collection time (00:00-23:59)

13:25 (24 HR)

Collection date and time (derived)

06 JAN 2021 13:25

US3992037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	13:27
Collection Date and Time (derived)	06 JAN 2021 13:27

US3992037

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

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992037

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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)	05 FEB 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 13:46
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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)	05 FEB 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 14:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3992037

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3992037

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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) 05 FEB 2021

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 14:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3992037

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992037

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:02:08

Generated On: 10 Jun 2021 10:41:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 20:02:08

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 11:05
Temperature (<i>xxx.x</i>)	35.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (<i>xxx</i>)	89 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992037

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:02:08

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3992037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 20:02:08

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

09 MAR 2021 11:10

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Visit Date	13 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Visit Date	14 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	08:15 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 08:15
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Visit Date	14 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:42:56

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3992037

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 15:40:34

Generated On: 10 Jun 2021 10:41:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

AEID

Adverse event

PLEURITIC CHEST PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

351 of 2020

EAB) (1725)

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

AEID	USA-US219-2021-MRNA-1273-P30 1000002
Adverse event	ACUTE APPENDICITIS
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)	10 JAN 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)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	14 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2020

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

PATIENT FELT UNWELL. SCAN
AT URGENT AID CLINIC
INDICATED APPENDICITIS.
PATIENT HAD APPENDECTOMY
ON 13/JAN/2021. MEDICAL
RECORDS HAVE BEEN
REQUESTED. MORE INFO WILL
FOLLOW. ADDENDUM:
PERFORMED CT SCAN
ABD/PELVIS, LAPAROSCOPIC
APPENDECTOMY WAS
PERFORMED. PATIENT
DISCHARGED HOME ON
1/14/2021.

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

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

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

Yes ☒

No ☐

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

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

Name of Medication OXYCODONE HCL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN;
OP-RELATED PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2020

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 JAN 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 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"/>

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN, POST
OP-RELATED PAIN

Dose per administration 650

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)

359 of 2020

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 JAN 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 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"/>

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication PRE-OPERATIVE ANESTHESIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify 2%

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2020

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

	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 checked="" 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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

Name of Medication MERCAINE

Prophylaxis Yes ☐
No ☒

Indication PRE-OPERATIVE ANESTHESIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify 0.5%

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2020

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Mar 2021 21:20:23

Generated On: 10 Jun 2021 10:41:11

	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 checked="" 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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	LAPAROSCOPIC APPENDECTOMY	Adverse Event	
13 JAN 2021	CT SCAN ABDOMEN/PELVIS	Diagnostic	

US3992037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:41:11

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

US3992037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:41:11

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 ☐

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/JAN/2021 07:25
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

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/JAN/2021 08:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/JAN/2021 17:17
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

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:28
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

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Feb 2021 22:42:55

Generated On: 10 Jun 2021 10:41:11

SAEID	USA-US219-2021-MRNA-1273-P301000002
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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:09
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

US3992037 (Prod: University of Chicago)

US3992037

Form: Participant Creation

Generated On: 10 Jun 2021 10:41:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'US3992037'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:08

US3992037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:10

US3992037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:09

US3992037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)'	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:10

US3992037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'SCRN'	System	26 Sep 2020 16:57:10

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered (b) (6) 1996'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:10

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '23'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'YEARS'	System	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered '23'	System	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Male (M)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'I'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4)	
	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26
	(b) (4)	

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:41:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:26

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'Sep 2020'	System	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered '2020'	System	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Amendment 3 (3)'	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4)	
	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44
	(b) (4)	

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:57:44

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:09

US3992037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:41:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'I'	System	26 Sep 2020 16:57:49

US3992037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4)	
	Kathleen Mullane (b) (4)	26 Sep 2020 16:57:49
	(b) (4)	

US3992037

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:41:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:58:01

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Oct 2020 16:33:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Oct 2020 16:33:14
User entered '10:00' reason for change: New Information	Karen Cornelius (b) (4)	02 Oct 2020 16:33:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	27 Sep 2020 14:28:18
User entered empty.	Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered '26 Sep 2020 10:00'	System	02 Oct 2020 16:33:14
User entered empty.	System	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '65' in	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:28:18
	(b) (4)	
DataPoint set to visible.	System	26 Sep 2020 16:57:49

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '125' lb	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18
DataPoint set to visible.	(b) (4) System	26 Sep 2020 16:57:49

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered '20.84458'	System	27 Sep 2020 14:28:18
DataPoint set to visible.	System	26 Sep 2020 16:57:49

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'kg/m2'	System	27 Sep 2020 14:28:18
DataPoint set to visible.	System	26 Sep 2020 16:57:49

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'bpm'	System	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'breaths/min'	System	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'mmHg'	System	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User entered 'mmHg'	System	27 Sep 2020 14:28:18

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23

US3992037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23

US3992037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:27

US3992037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:27

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'I'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:41:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:23
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:22:11

US3992037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:39

US3992037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:39

US3992037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:39

US3992037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'VISIT1'	System	26 Sep 2020 16:59:39

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:11

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '115702'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:11

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:01:11

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55

US3992037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	(b) (4)	
	Kathleen Mullane (b) (4)	26 Sep 2020 16:59:55
	(b) (4)	
DataPoint set to visible.	System	26 Sep 2020 16:57:44

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	02 Oct 2020 16:34:02
data change (Site from System).		02 Oct 2020 16:34:02
User entered '10:00' reason for change: Data Entry Error	Karen Cornelius (b) (4)	02 Oct 2020 16:34:02
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	27 Sep 2020 14:30:46
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:46
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 10:00'	System	02 Oct 2020 16:34:02
User entered empty.	System	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:46:27
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:31:27
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	27 Sep 2020 14:30:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Sep 2020 14:30:55
User entered '35.7' C reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:30:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Sep 2020 14:30:46
User entered '35.7' (non-conformant).	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'tympanic'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '85'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'bpm'	System	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM). Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'ncs' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:03:53
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM). User entered '20'	Karen Cornelius (b) (4)	18 Nov 2020 19:27:53
	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:21:34
	(b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'breaths/min'	System	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '122'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '75'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:30:46

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Sep 2020 14:33:23
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Sep 2020 14:30:55
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Oct 2020 16:34:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 16:34:22
User entered '12:17' reason for change: New Information	Karen Cornelius (b) (4)	02 Oct 2020 16:34:22
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	27 Sep 2020 14:33:23
User entered empty.	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 12:17'	System	02 Oct 2020 16:34:22
User entered empty.	System	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '98.3' F reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'tympanic' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '82' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'bpm'	System	27 Sep 2020 14:33:23
User entered empty.	System	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'breaths/min'	System	27 Sep 2020 14:33:23
User entered empty.	System	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '119' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	27 Sep 2020 14:33:23
User entered empty.	System	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '77' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:23
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	27 Sep 2020 14:30:55
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	27 Sep 2020 14:33:23
User entered empty.	System	27 Sep 2020 14:30:55

US3992037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 13:41:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	29 Sep 2020 13:41:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Sep 2020 14:33:40
	Karen Cornelius (b) (4)	27 Sep 2020 14:33:40
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:33:40
	(b) (4)	

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '11:47'	(b) (4) Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 11:47'	System	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Left Arm (LEFT ARM)'	Kathleen Mullane (b) (4)	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'ONCE'	System	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 17:00:36

US3992037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:13

US3992037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:13

US3992037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '11:01'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:13

US3992037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 11:01'	System	27 Sep 2020 14:34:13

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '26 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '11:03'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 11:03'	System	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Cornelius (b) (4) (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '11:03'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '26 Sep 2020 11:03'	System	27 Sep 2020 14:34:43

US3992037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	27 Sep 2020 14:34:52

US3992037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'I'	System	27 Sep 2020 14:34:52

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:19:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd7132ec0-6cd6-4bfb-828c-37f38141fbf5' User entered 'Yes (Y)'	System	26 Sep 2020 17:20:08
	System	26 Sep 2020 17:20:08

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:19:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd7132ec0-6cd6-4bfb-828c-37f38141fbf5' User entered '98.3'	System	26 Sep 2020 17:20:08
	System	26 Sep 2020 17:20:08

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:19:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd7132ec0-6cd6-4bfb-828c-37f38141fbf5'	System	26 Sep 2020 17:20:08
User entered 'No (N)'	System	26 Sep 2020 17:20:08

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:04', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd7132ec0-6cd6-4bfb-828c-37f38141fbf5'	System	26 Sep 2020 17:20:08
User entered '26 Sep 2020 12:20'	System	26 Sep 2020 17:20:08

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 12:07'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 14:37'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:25:33', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a36f1e-f820-4417-9498-c4974029c1d2'	System	27 Sep 2020 04:25:44
User entered 'Yes (Y)'	System	27 Sep 2020 04:25:44

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:25:38', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a36f1e-f820-4417-9498-c4974029c1d2' User entered '97.2'	System	27 Sep 2020 04:25:44
	System	27 Sep 2020 04:25:44

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:25:40', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a36f1e-f820-4417-9498-c4974029c1d2'	System	27 Sep 2020 04:25:44
User entered 'No (N)'	System	27 Sep 2020 04:25:44

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:25:42', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a36f1e-f820-4417-9498-c4974029c1d2'	System	27 Sep 2020 04:25:44
User entered '26 Sep 2020 23:25'	System	27 Sep 2020 04:25:44

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 15:32'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 2'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:34:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '9d2d2d73-dd0b-44d0-83a3-1afc6b2d9c1a' User entered 'Yes (Y)'	System	28 Sep 2020 05:34:57
	System	28 Sep 2020 05:34:57

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:34:51', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '9d2d2d73-dd0b-44d0-83a3-1afc6b2d9c1a' User entered '97.9'	System	28 Sep 2020 05:34:57
	System	28 Sep 2020 05:34:57

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:34:53', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '9d2d2d73-dd0b-44d0-83a3-1afc6b2d9c1a' User entered 'No (N)'	System	28 Sep 2020 05:34:57
	System	28 Sep 2020 05:34:57

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:34:55', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '9d2d2d73-dd0b-44d0-83a3-1afc6b2d9c1a' User entered '28 Sep 2020 00:34'	System	28 Sep 2020 05:34:57
	System	28 Sep 2020 05:34:57

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 3'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:10', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0eb22cc-0955-49e9-87dc-3bf9b181f8fe' User entered 'Yes (Y)'	System	29 Sep 2020 06:03:28
	System	29 Sep 2020 06:03:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:14', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0eb22cc-0955-49e9-87dc-3bf9b181f8fe' User entered '97.2'	System	29 Sep 2020 06:03:28
	System	29 Sep 2020 06:03:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:21', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0eb22cc-0955-49e9-87dc-3bf9b181f8fe'	System	29 Sep 2020 06:03:28
User entered 'No (N)'	System	29 Sep 2020 06:03:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:27', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0eb22cc-0955-49e9-87dc-3bf9b181f8fe' User entered '29 Sep 2020 01:03'	System	29 Sep 2020 06:03:28
	System	29 Sep 2020 06:03:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 4'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:30', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a4ec89-d2c5-403d-a3d9-a0245e804c13' User entered 'Yes (Y)'	System	30 Sep 2020 06:47:42
	System	30 Sep 2020 06:47:42

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a4ec89-d2c5-403d-a3d9-a0245e804c13' User entered '98.3'	System	30 Sep 2020 06:47:42
	System	30 Sep 2020 06:47:42

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:37', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a4ec89-d2c5-403d-a3d9-a0245e804c13' User entered 'No (N)'	System	30 Sep 2020 06:47:42
	System	30 Sep 2020 06:47:42

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:39', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65a4ec89-d2c5-403d-a3d9-a0245e804c13' User entered '30 Sep 2020 01:47'	System	30 Sep 2020 06:47:42
	System	30 Sep 2020 06:47:42

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 5'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-01T00:13:06', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c86f14ba-f05f-4ab3-85f6-acfeb17602e4' User entered 'Yes (Y)'	System	01 Oct 2020 05:13:28
	System	01 Oct 2020 05:13:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-01T00:13:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c86f14ba-f05f-4ab3-85f6-acfeb17602e4' User entered '98.6'	System	01 Oct 2020 05:13:28
	System	01 Oct 2020 05:13:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-01T00:13:15', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c86f14ba-f05f-4ab3-85f6-acfeb17602e4'	System	01 Oct 2020 05:13:28
User entered 'No (N)'	System	01 Oct 2020 05:13:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-01T00:13:25', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c86f14ba-f05f-4ab3-85f6-acfeb17602e4' User entered '01 Oct 2020 00:13'	System	01 Oct 2020 05:13:28
	System	01 Oct 2020 05:13:28

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 6'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:40', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3d778ae4-7fe6-435c-b26d-75f0a3138937' User entered 'Yes (Y)'	System	02 Oct 2020 06:07:55
	System	02 Oct 2020 06:07:55

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3d778ae4-7fe6-435c-b26d-75f0a3138937' User entered '97.5'	System	02 Oct 2020 06:07:55
	System	02 Oct 2020 06:07:55

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3d778ae4-7fe6-435c-b26d-75f0a3138937'	System	02 Oct 2020 06:07:55
User entered 'No (N)'	System	02 Oct 2020 06:07:55

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:51', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3d778ae4-7fe6-435c-b26d-75f0a3138937' User entered '02 Oct 2020 01:07'	System	02 Oct 2020 06:07:55
	System	02 Oct 2020 06:07:55

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 7'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'f615712d-e98f-4ac4-84e1-0fc149062446'	System	26 Sep 2020 17:20:45
User entered 'None (1)'	System	26 Sep 2020 17:20:45

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:34', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'f615712d-e98f-4ac4-84e1-0fc149062446' User entered 'No (N)'	System	26 Sep 2020 17:20:45
	System	26 Sep 2020 17:20:45

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'f615712d-e98f-4ac4-84e1-0fc149062446'	System	26 Sep 2020 17:20:45
User entered 'No (N)'	System	26 Sep 2020 17:20:45

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:39', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'f615712d-e98f-4ac4-84e1-0fc149062446'	System	26 Sep 2020 17:20:45
User entered 'None (1)'	System	26 Sep 2020 17:20:45

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:42', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'f615712d-e98f-4ac4-84e1-0fc149062446'	System	26 Sep 2020 17:20:45
User entered '26 Sep 2020 12:20'	System	26 Sep 2020 17:20:45

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 12:07'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 14:37'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'cf4cc01a-6786-49f5-b198-adbe55b04459'	System	27 Sep 2020 04:22:08
User entered 'None (1)'	System	27 Sep 2020 04:22:08

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:22:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'cf4cc01a-6786-49f5-b198-adbe55b04459'	System	27 Sep 2020 04:22:08
User entered 'No (N)'	System	27 Sep 2020 04:22:08

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:22:02', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'cf4cc01a-6786-49f5-b198-adbe55b04459'	System	27 Sep 2020 04:22:08
User entered 'No (N)'	System	27 Sep 2020 04:22:08

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:22:03', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'cf4cc01a-6786-49f5-b198-adbe55b04459'	System	27 Sep 2020 04:22:08
User entered 'None (1)'	System	27 Sep 2020 04:22:08

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:22:06', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'cf4cc01a-6786-49f5-b198-adbe55b04459' User entered '26 Sep 2020 23:22'	System	27 Sep 2020 04:22:08
	System	27 Sep 2020 04:22:08

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 15:32'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 2'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd1225b83-e7d5-45e2-9481-eb1117080512'	System	28 Sep 2020 05:32:58
User entered 'None (1)'	System	28 Sep 2020 05:32:58

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd1225b83-e7d5-45e2-9481-eb1117080512'	System	28 Sep 2020 05:32:58
User entered 'No (N)'	System	28 Sep 2020 05:32:58

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd1225b83-e7d5-45e2-9481-eb1117080512'	System	28 Sep 2020 05:32:58
User entered 'No (N)'	System	28 Sep 2020 05:32:58

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd1225b83-e7d5-45e2-9481-eb1117080512'	System	28 Sep 2020 05:32:58
User entered 'None (1)'	System	28 Sep 2020 05:32:58

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:56', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd1225b83-e7d5-45e2-9481-eb1117080512'	System	28 Sep 2020 05:32:58
User entered '28 Sep 2020 00:32'	System	28 Sep 2020 05:32:58

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 3'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:34', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '214437c9-4ccf-43ae-9370-725536344347'	System	29 Sep 2020 06:03:48
User entered 'None (1)'	System	29 Sep 2020 06:03:48

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:38', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '214437c9-4ccf-43ae-9370-725536344347'	System	29 Sep 2020 06:03:48
User entered 'No (N)'	System	29 Sep 2020 06:03:48

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:40', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '214437c9-4ccf-43ae-9370-725536344347' User entered 'No (N)'	System	29 Sep 2020 06:03:48
	System	29 Sep 2020 06:03:48

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:42', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '214437c9-4ccf-43ae-9370-725536344347' User entered 'None (1)'	System	29 Sep 2020 06:03:48
	System	29 Sep 2020 06:03:48

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '214437c9-4ccf-43ae-9370-725536344347' User entered '29 Sep 2020 01:03'	System	29 Sep 2020 06:03:48
	System	29 Sep 2020 06:03:48

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 4'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c296178-8709-4eb5-bb56-7d4e617653ea'	System	30 Sep 2020 06:47:52
User entered 'None (1)'	System	30 Sep 2020 06:47:52

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c296178-8709-4eb5-bb56-7d4e617653ea' User entered 'No (N)'	System	30 Sep 2020 06:47:52
	System	30 Sep 2020 06:47:52

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:46', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c296178-8709-4eb5-bb56-7d4e617653ea' User entered 'No (N)'	System	30 Sep 2020 06:47:52
	System	30 Sep 2020 06:47:52

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:48', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c296178-8709-4eb5-bb56-7d4e617653ea' User entered 'None (1)'	System	30 Sep 2020 06:47:52
	System	30 Sep 2020 06:47:52

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c296178-8709-4eb5-bb56-7d4e617653ea' User entered '30 Sep 2020 01:47'	System	30 Sep 2020 06:47:52
	System	30 Sep 2020 06:47:52

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 5'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:34', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '732d5844-a8d2-4f1f-920c-adc07545c73c'	System	01 Oct 2020 04:59:46
User entered 'None (1)'	System	01 Oct 2020 04:59:46

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:37', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '732d5844-a8d2-4f1f-920c-adc07545c73c'	System	01 Oct 2020 04:59:46
User entered 'No (N)'	System	01 Oct 2020 04:59:46

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:38', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '732d5844-a8d2-4f1f-920c-adc07545c73c' User entered 'No (N)'	System	01 Oct 2020 04:59:46
	System	01 Oct 2020 04:59:46

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:40', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '732d5844-a8d2-4f1f-920c-adc07545c73c'	System	01 Oct 2020 04:59:46
User entered 'None (1)'	System	01 Oct 2020 04:59:46

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:43', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '732d5844-a8d2-4f1f-920c-adc07545c73c'	System	01 Oct 2020 04:59:46
User entered '30 Sep 2020 23:59'	System	01 Oct 2020 04:59:46

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 6'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:28', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c46f49-0b00-4008-992f-c8aa19fe4d69'	System	02 Oct 2020 06:07:40
User entered 'None (1)'	System	02 Oct 2020 06:07:40

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:29', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c46f49-0b00-4008-992f-c8aa19fe4d69'	System	02 Oct 2020 06:07:40
User entered 'No (N)'	System	02 Oct 2020 06:07:40

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:31', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c46f49-0b00-4008-992f-c8aa19fe4d69'	System	02 Oct 2020 06:07:40
User entered 'No (N)'	System	02 Oct 2020 06:07:40

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:32', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c46f49-0b00-4008-992f-c8aa19fe4d69'	System	02 Oct 2020 06:07:40
User entered 'None (1)'	System	02 Oct 2020 06:07:40

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c46f49-0b00-4008-992f-c8aa19fe4d69'	System	02 Oct 2020 06:07:40
User entered '02 Oct 2020 01:07'	System	02 Oct 2020 06:07:40

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 7'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:46', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:53', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'None (0)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:20:59', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered 'No (N)'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T12:21:02', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '648f4469-dd5d-4865-9001-d0b05943879e' User entered '26 Sep 2020 12:21'	System	26 Sep 2020 17:21:06
	System	26 Sep 2020 17:21:06

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 12:07'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 14:37'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:43', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:45', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:46', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:48', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'None (0)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered 'No (N)'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-26T23:21:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd880a342-fb2a-4b75-9dff-4809453d70e4' User entered '26 Sep 2020 23:21'	System	27 Sep 2020 04:21:57
	System	27 Sep 2020 04:21:57

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '26 Sep 2020 15:32'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 2'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:16', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:19', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:22', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:24', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:26', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:29', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'None (0)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered 'No (N)'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-28T00:32:38', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'bf5a3d35-cc2d-4596-ae07-d0c46101bb4b' User entered '28 Sep 2020 00:32'	System	28 Sep 2020 05:32:40
	System	28 Sep 2020 05:32:40

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 3'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T00:00:24', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:51', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:55', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:03:57', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'None (0)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:04:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered 'No (N)'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-29T01:04:16', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '2e58372a-e3ff-4dfb-a733-3062a9984779' User entered '29 Sep 2020 01:04'	System	29 Sep 2020 06:04:20
	System	29 Sep 2020 06:04:20

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 4'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:55', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:57', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:47:59', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:48:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:48:01', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'None (0)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:48:03', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered 'No (N)'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T01:48:05', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '71522f6a-36ad-465e-84d7-f3e4c4626726' User entered '30 Sep 2020 01:48'	System	30 Sep 2020 06:48:08
	System	30 Sep 2020 06:48:08

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 5'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:16', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:20', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:22', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:23', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:24', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'None (0)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:28', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered 'No (N)'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-09-30T23:59:31', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '523fd78e-dc93-40df-b057-e2f1a60fead1' User entered '30 Sep 2020 23:59'	System	01 Oct 2020 04:59:36
	System	01 Oct 2020 04:59:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 6'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:14', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:16', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:19', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:20', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'None (0)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:23', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered 'No (N)'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-02T01:07:25', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '689d205b-9b03-4a0a-b23d-09f317c2e960' User entered '02 Oct 2020 01:07'	System	02 Oct 2020 06:07:30
	System	02 Oct 2020 06:07:30

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	26 Sep 2020 17:00:36
User entered 'Day 7'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:00:36

US3992037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:00:36

US3992037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:37:16

US3992037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '3 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:37:16

US3992037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:37:16

US3992037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:37:16
	(b) (4)	

US3992037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:37:38

US3992037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	20 Oct 2020 14:37:38

US3992037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:01

US3992037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '10 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:01

US3992037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:01

US3992037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:01

US3992037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:06

US3992037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	20 Oct 2020 14:38:06

US3992037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:30

US3992037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '17 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:30

US3992037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:30

US3992037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:30
	(b) (4)	

US3992037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:38:37

US3992037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	20 Oct 2020 14:38:37

US3992037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:24:55

US3992037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4)	
	Kathleen Mullane (b) (4)	30 Oct 2020 14:24:55
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)'	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:24:55
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'VISIT2'	System	30 Oct 2020 14:24:55

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '08:28'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 08:28'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:47:35
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:28:17
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Nov 2020 17:27:56
User entered '35.4' C	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '74'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'bpm'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '18'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'breaths/min'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '121'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '72'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '09:50'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 09:50'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:47:43
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:28:27
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Nov 2020 17:27:56
User entered '35.7' C	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '71'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'bpm'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query ' Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM). Query ' Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'ncs' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:04:26
User opened query ' Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	Karen Cornelius (b) (4)	18 Nov 2020 19:29:13
User entered '18'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:22:38
	(b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'breaths/min'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '110'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '70'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	01 Nov 2020 17:27:56

US3992037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:26:29

US3992037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:26:29

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'MRNA-1273 OR PLACEBO'	System	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '9:20'	(b) (4) Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18
	(b) (4)	

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 9:20'	System	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Left Arm (LEFT ARM)'	Kathleen Mullane (b) (4)	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'ONCE'	System	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'INTRAMUSCULAR'	System	30 Oct 2020 14:25:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 09:50:46
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'correct as entered' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	18 Nov 2020 19:28:21
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:12:29
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:26:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:26:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '08:42'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:26:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 08:42'	System	01 Nov 2020 17:26:18

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '30 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '08:45'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 08:45'	System	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Cornelius (b) (4) (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '08:45'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '30 Oct 2020 08:45'	System	01 Nov 2020 17:25:47

US3992037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	01 Nov 2020 17:25:57

US3992037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'I'	System	01 Nov 2020 17:25:57

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd94d97b2-9936-400c-9696-43a18c55b9e2'	System	30 Oct 2020 14:52:11
User entered 'Yes (Y)'	System	30 Oct 2020 14:52:11

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:04', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd94d97b2-9936-400c-9696-43a18c55b9e2'	System	30 Oct 2020 14:52:11
User entered '96.2'	System	30 Oct 2020 14:52:11

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:06', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd94d97b2-9936-400c-9696-43a18c55b9e2'	System	30 Oct 2020 14:52:11
User entered 'No (N)'	System	30 Oct 2020 14:52:11

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'd94d97b2-9936-400c-9696-43a18c55b9e2'	System	30 Oct 2020 14:52:11
User entered '30 Oct 2020 09:52'	System	30 Oct 2020 14:52:11

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 09:40'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 12:10'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 13:05'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 2'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-01T01:03:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'a1574a29-9598-4721-b195-d620ddfb29f2'	System	01 Nov 2020 07:03:58
User entered 'Yes (Y)'	System	01 Nov 2020 07:03:58

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-01T01:03:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'a1574a29-9598-4721-b195-d620ddfb29f2' User entered '97.6'	System	01 Nov 2020 07:03:58
	System	01 Nov 2020 07:03:58

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-01T01:03:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'a1574a29-9598-4721-b195-d620ddfb29f2'	System	01 Nov 2020 07:03:58
User entered 'No (N)'	System	01 Nov 2020 07:03:58

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-01T01:03:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'a1574a29-9598-4721-b195-d620ddfb29f2'	System	01 Nov 2020 07:03:58
User entered '01 Nov 2020 01:03'	System	01 Nov 2020 07:03:58

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 3'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 4'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 5'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T16:30:08', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7f5cf0f2-0f1f-4e99-8993-70b32d157c11'	System	03 Nov 2020 22:30:43
User entered 'Yes (Y)'	System	03 Nov 2020 22:30:43

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T16:30:36', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7f5cf0f2-0f1f-4e99-8993-70b32d157c11' User entered '96.7'	System	03 Nov 2020 22:30:43
	System	03 Nov 2020 22:30:43

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T16:30:38', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7f5cf0f2-0f1f-4e99-8993-70b32d157c11'	System	03 Nov 2020 22:30:43
User entered 'No (N)'	System	03 Nov 2020 22:30:43

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T16:30:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7f5cf0f2-0f1f-4e99-8993-70b32d157c11' User entered '03 Nov 2020 16:30'	System	03 Nov 2020 22:30:43
	System	03 Nov 2020 22:30:43

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 6'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8082d87f-229e-40cc-b0a8-fab868e39d27'	System	05 Nov 2020 05:51:46
User entered 'Yes (Y)'	System	05 Nov 2020 05:51:46

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:39', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8082d87f-229e-40cc-b0a8-fab868e39d27' User entered '97.3'	System	05 Nov 2020 05:51:46
	System	05 Nov 2020 05:51:46

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8082d87f-229e-40cc-b0a8-fab868e39d27'	System	05 Nov 2020 05:51:46
User entered 'No (N)'	System	05 Nov 2020 05:51:46

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8082d87f-229e-40cc-b0a8-fab868e39d27'	System	05 Nov 2020 05:51:46
User entered '04 Nov 2020 23:51'	System	05 Nov 2020 05:51:46

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 7'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:39', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7e089f7e-f140-44e0-9534-9e9f34cf5f3b' User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 14:52:49
	System	30 Oct 2020 14:52:49

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7e089f7e-f140-44e0-9534-9e9f34cf5f3b' User entered 'No (N)'	System	30 Oct 2020 14:52:49
	System	30 Oct 2020 14:52:49

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:42', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7e089f7e-f140-44e0-9534-9e9f34cf5f3b'	System	30 Oct 2020 14:52:49
User entered 'No (N)'	System	30 Oct 2020 14:52:49

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:45', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7e089f7e-f140-44e0-9534-9e9f34cf5f3b'	System	30 Oct 2020 14:52:49
User entered 'None (1)'	System	30 Oct 2020 14:52:49

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7e089f7e-f140-44e0-9534-9e9f34cf5f3b' User entered '30 Oct 2020 09:52'	System	30 Oct 2020 14:52:49
	System	30 Oct 2020 14:52:49

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 09:40'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 12:10'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 13:05'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 2'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '44a97a41-e3be-4f19-a47c-52e051631d86'	System	01 Nov 2020 04:57:53
User entered 'None (1)'	System	01 Nov 2020 04:57:53

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:45', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '44a97a41-e3be-4f19-a47c-52e051631d86'	System	01 Nov 2020 04:57:53
User entered 'No (N)'	System	01 Nov 2020 04:57:53

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:46', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '44a97a41-e3be-4f19-a47c-52e051631d86'	System	01 Nov 2020 04:57:53
User entered 'No (N)'	System	01 Nov 2020 04:57:53

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:48', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '44a97a41-e3be-4f19-a47c-52e051631d86'	System	01 Nov 2020 04:57:53
User entered 'None (1)'	System	01 Nov 2020 04:57:53

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '44a97a41-e3be-4f19-a47c-52e051631d86' User entered '31 Oct 2020 23:57'	System	01 Nov 2020 04:57:53
	System	01 Nov 2020 04:57:53

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 3'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 4'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 5'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:48', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b6b56db8-94cd-4ff8-a538-12285e4ff3ab'	System	03 Nov 2020 20:49:59
User entered 'None (1)'	System	03 Nov 2020 20:49:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b6b56db8-94cd-4ff8-a538-12285e4ff3ab' User entered 'No (N)'	System	03 Nov 2020 20:49:59
	System	03 Nov 2020 20:49:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b6b56db8-94cd-4ff8-a538-12285e4ff3ab' User entered 'No (N)'	System	03 Nov 2020 20:49:59
	System	03 Nov 2020 20:49:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:53', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b6b56db8-94cd-4ff8-a538-12285e4ff3ab' User entered 'None (1)'	System	03 Nov 2020 20:49:59
	System	03 Nov 2020 20:49:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:55', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b6b56db8-94cd-4ff8-a538-12285e4ff3ab' User entered '03 Nov 2020 14:49'	System	03 Nov 2020 20:49:59
	System	03 Nov 2020 20:49:59

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 6'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:47', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0881970-02b0-40f6-976f-a8cbea0786ef'	System	05 Nov 2020 05:51:56
User entered 'None (1)'	System	05 Nov 2020 05:51:56

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0881970-02b0-40f6-976f-a8cbea0786ef' User entered 'No (N)'	System	05 Nov 2020 05:51:56
	System	05 Nov 2020 05:51:56

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0881970-02b0-40f6-976f-a8cbea0786ef' User entered 'No (N)'	System	05 Nov 2020 05:51:56
	System	05 Nov 2020 05:51:56

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:52', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0881970-02b0-40f6-976f-a8cbea0786ef' User entered 'None (1)'	System	05 Nov 2020 05:51:56
	System	05 Nov 2020 05:51:56

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'b0881970-02b0-40f6-976f-a8cbea0786ef' User entered '04 Nov 2020 23:51'	System	05 Nov 2020 05:51:56
	System	05 Nov 2020 05:51:56

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 7'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:12', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:15', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:20', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:21', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'None (0)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:32', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered 'No (N)'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-30T09:52:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8eeb2815-5d04-4dcf-ab0f-ad8c80b33f01' User entered '30 Oct 2020 09:52'	System	30 Oct 2020 14:52:38
	System	30 Oct 2020 14:52:38

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 09:40'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 12:10'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '30 Oct 2020 13:05'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 2'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:55', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:56', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:57', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:57:59', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:58:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'None (0)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:58:05', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered 'No (N)'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-10-31T23:58:07', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '990787e6-856b-4b40-8d87-106fe63e4791' User entered '31 Oct 2020 23:58'	System	01 Nov 2020 04:58:11
	System	01 Nov 2020 04:58:11

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 3'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 4'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 5'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:49:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:02', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:04', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:06', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:07', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'None (0)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered 'No (N)'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-03T14:50:11', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c54b066c-37ec-44f5-8242-394df638ee60' User entered '03 Nov 2020 14:50'	System	03 Nov 2020 20:50:16
	System	03 Nov 2020 20:50:16

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 6'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:51:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:01', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:02', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:04', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:05', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'None (0)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:07', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered 'No (N)'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-11-04T23:52:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f56359-46df-45d6-903a-e2c24466a654' User entered '04 Nov 2020 23:52'	System	05 Nov 2020 05:52:13
	System	05 Nov 2020 05:52:13

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
Data entry locked.	System	30 Oct 2020 14:25:18
User entered 'Day 7'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

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)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:25:18

US3992037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:41:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:01:39
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:25:18

US3992037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:14

US3992037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '6 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:14

US3992037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:14

US3992037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:14
	(b) (4)	

US3992037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:35
	(b) (4)	

US3992037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	16 Nov 2020 13:29:35

US3992037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:59

US3992037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:59
	(b) (4)	

US3992037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:59

US3992037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:29:59
	(b) (4)	

US3992037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	16 Nov 2020 13:30:04

US3992037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	16 Nov 2020 13:30:04

US3992037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	22 Nov 2020 16:38:51

US3992037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '20 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	22 Nov 2020 16:38:51

US3992037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	22 Nov 2020 16:38:51

US3992037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Nov 2020 16:38:51

US3992037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	22 Nov 2020 16:38:56

US3992037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	22 Nov 2020 16:38:56

US3992037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:07:11
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	06 Jan 2021 17:07:51
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:16:09
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'D57 performed with un-blinding ' (Site from System).	Karen Cornelius (b) (4) (b) (4)	29 Jan 2021 20:07:42
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Jan 2021 20:07:11
User entered '06 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	29 Jan 2021 20:07:11
User entered empty.	Karen Cornelius (b) (4) (b) (4)	06 Jan 2021 17:07:51

US3992037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Karen Cornelius (b) (4)	29 Jan 2021 20:07:11
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:07:51
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'VISIT3'	System	06 Jan 2021 17:07:51

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:21' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '06 Jan 2021 13:21'	System	29 Jan 2021 20:09:03
User entered empty.	System	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '36.9' C reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '87' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'bpm'	System	29 Jan 2021 20:09:03
User entered empty.	System	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Per CDM: Per CCG V3.0 page 60, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 09:42:02
Query 'Per CDM: Per CCG V3.0 page 60, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'ncs' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	08 Feb 2021 17:53:17
User opened query 'Per CDM: Per CCG V3.0 page 60, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:02:12
User entered '18' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	29 Jan 2021 20:09:03
User entered empty.	Karen Cornelius (b) (4) (b) (4)	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'breaths/min'	System	29 Jan 2021 20:09:03
User entered empty.	System	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '120' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	29 Jan 2021 20:09:03
User entered empty.	System	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '66' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	29 Jan 2021 20:09:03
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	06 Jan 2021 17:09:23
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered 'mmHg'	System	29 Jan 2021 20:09:03
User entered empty.	System	06 Jan 2021 17:09:23

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33

US3992037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33

US3992037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:17

US3992037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:17

US3992037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:35

US3992037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:35
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:25'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:35
	(b) (4)	

US3992037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '06 Jan 2021 13:25'	System	29 Jan 2021 20:09:35

US3992037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:09:42

US3992037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:33
User entered '1'	System	29 Jan 2021 20:09:42

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-02T15:56:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '11348ac1-1cff-42e7-8589-69474a3943af' User entered 'No (N)'	System	02 Dec 2020 20:56:23
	System	02 Dec 2020 20:56:23

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-02T15:56:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '11348ac1-1cff-42e7-8589-69474a3943af'	System	02 Dec 2020 20:56:23
User entered 'No (N)'	System	02 Dec 2020 20:56:23

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-02T15:56:21', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '11348ac1-1cff-42e7-8589-69474a3943af' User entered '02 Dec 2020 15:56:21'	System	02 Dec 2020 20:56:23
	System	02 Dec 2020 20:56:23

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-09T12:00:10', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '533c1b20-b41e-4443-bfa9-6532c7b5620f' User entered 'No (N)'	System	09 Dec 2020 17:00:17
	System	09 Dec 2020 17:00:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-09T12:00:12', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '533c1b20-b41e-4443-bfa9-6532c7b5620f' User entered 'No (N)'	System	09 Dec 2020 17:00:17
	System	09 Dec 2020 17:00:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-09T12:00:14', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '533c1b20-b41e-4443-bfa9-6532c7b5620f' User entered '09 Dec 2020 12:00:14'	System	09 Dec 2020 17:00:17
	System	09 Dec 2020 17:00:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-14T21:36:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'be5f9b50-9135-45ad-ac11-469e0d512f8c'	System	15 Dec 2020 02:36:56
User entered 'No (N)'	System	15 Dec 2020 02:36:56

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-14T21:36:51', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'be5f9b50-9135-45ad-ac11-469e0d512f8c'	System	15 Dec 2020 02:36:56
User entered 'No (N)'	System	15 Dec 2020 02:36:56

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-14T21:36:54', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'be5f9b50-9135-45ad-ac11-469e0d512f8c' User entered '14 Dec 2020 21:36:54'	System	15 Dec 2020 02:36:56
	System	15 Dec 2020 02:36:56

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:00:22', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'Yes (Y)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:00:28', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'No (N)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:00:31', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'Yes (Y)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '1'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:09', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '0'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Please 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:15', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'Yes (Y)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Please 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:21', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34'	System	30 Dec 2020 17:01:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2020-12-30T12:01:36', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '8821b91a-d098-4d46-8bf0-7f0ba7777b34' User entered '30 Dec 2020 12:01:36'	System	30 Dec 2020 17:01:47
	System	30 Dec 2020 17:01:47

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-04T00:01:14', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '80f81f5a-3b82-4b71-9a64-34c87acf1a13'	System	04 Jan 2021 05:01:37
User entered 'Yes (Y)'	System	04 Jan 2021 05:01:37

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-04T00:01:18', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '80f81f5a-3b82-4b71-9a64-34c87acf1a13'	System	04 Jan 2021 05:01:37
User entered 'No (N)'	System	04 Jan 2021 05:01:37

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-04T00:01:23', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '80f81f5a-3b82-4b71-9a64-34c87acf1a13'	System	04 Jan 2021 05:01:37
User entered 'No (N)'	System	04 Jan 2021 05:01:37

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-04T00:01:29', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '80f81f5a-3b82-4b71-9a64-34c87acf1a13'	System	04 Jan 2021 05:01:37
User entered 'No (N)'	System	04 Jan 2021 05:01:37

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-04T00:01:32', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '80f81f5a-3b82-4b71-9a64-34c87acf1a13'	System	04 Jan 2021 05:01:37
User entered '04 Jan 2021 00:01:32'	System	04 Jan 2021 05:01:37

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:13:44', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895'	System	13 Jan 2021 17:14:26
User entered 'Yes (Y)'	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:13:46', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895'	System	13 Jan 2021 17:14:26
User entered 'No (N)'	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:13:49', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895'	System	13 Jan 2021 17:14:26
User entered 'No (N)'	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:13:51', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895'	System	13 Jan 2021 17:14:26
User entered 'Yes (Y)'	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Please 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:13:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895'	System	13 Jan 2021 17:14:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-13T12:14:12', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '3c5bdd2c-8bfb-42d6-8f23-ff7310b9d895' User entered '13 Jan 2021 12:14:12'	System	13 Jan 2021 17:14:26
	System	13 Jan 2021 17:14:26

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-20T12:00:15', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7aa7ed95-1a56-4b37-b8e1-51d1af60bea1' User entered 'No (N)'	System	20 Jan 2021 17:00:41
	System	20 Jan 2021 17:00:41

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-20T12:00:16', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7aa7ed95-1a56-4b37-b8e1-51d1af60bea1'	System	20 Jan 2021 17:00:41
User entered 'No (N)'	System	20 Jan 2021 17:00:41

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-20T12:00:19', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7aa7ed95-1a56-4b37-b8e1-51d1af60bea1' User entered '20 Jan 2021 12:00:19'	System	20 Jan 2021 17:00:41
	System	20 Jan 2021 17:00:41

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-27T16:55:05', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '0c22a090-0802-4fdf-bdd9-bafb55f50ee0' User entered 'No (N)'	System	27 Jan 2021 21:55:16
	System	27 Jan 2021 21:55:16

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-27T16:55:11', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '0c22a090-0802-4fdf-bdd9-bafb55f50ee0' User entered 'No (N)'	System	27 Jan 2021 21:55:16
	System	27 Jan 2021 21:55:16

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-01-27T16:55:13', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '0c22a090-0802-4fdf-bdd9-bafb55f50ee0' User entered '27 Jan 2021 16:55:13'	System	27 Jan 2021 21:55:16
	System	27 Jan 2021 21:55:16

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-03T12:01:58', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'e3a6f0b4-f02d-450f-8d38-da106829bf60'	System	03 Feb 2021 17:05:36
User entered 'No (N)'	System	03 Feb 2021 17:05:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-03T12:02:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'e3a6f0b4-f02d-450f-8d38-da106829bf60'	System	03 Feb 2021 17:05:36
User entered 'No (N)'	System	03 Feb 2021 17:05:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-03T12:02:02', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'e3a6f0b4-f02d-450f-8d38-da106829bf60'	System	03 Feb 2021 17:05:36
User entered '03 Feb 2021 12:02:02'	System	03 Feb 2021 17:05:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-10T12:00:32', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '539fd7bb-6890-4944-8f60-752fa209bb6d' User entered 'No (N)'	System	10 Feb 2021 17:01:55
	System	10 Feb 2021 17:01:55

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-10T12:00:33', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '539fd7bb-6890-4944-8f60-752fa209bb6d' User entered 'No (N)'	System	10 Feb 2021 17:01:55
	System	10 Feb 2021 17:01:55

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-10T12:00:35', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '539fd7bb-6890-4944-8f60-752fa209bb6d' User entered '10 Feb 2021 12:00:35'	System	10 Feb 2021 17:01:55

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-17T16:32:41', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '22e45add-16ca-43b8-af76-019ae53dbc1d' User entered 'No (N)'	System	17 Feb 2021 21:32:54
	System	17 Feb 2021 21:32:54

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-17T16:32:48', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '22e45add-16ca-43b8-af76-019ae53dbc1d' User entered 'No (N)'	System	17 Feb 2021 21:32:54

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-17T16:32:50', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '22e45add-16ca-43b8-af76-019ae53dbc1d' User entered '17 Feb 2021 16:32:50'	System	17 Feb 2021 21:32:54
	System	17 Feb 2021 21:32:54

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-24T12:00:14-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c76525-cdca-4eb4-96d4-bdb656cdcd83'	System	03 Mar 2021 20:33:38
User entered 'No (N)'	System	03 Mar 2021 20:33:38

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-24T12:00:16-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c76525-cdca-4eb4-96d4-bdb656cdcd83'	System	03 Mar 2021 20:33:38
User entered 'No (N)'	System	03 Mar 2021 20:33:38

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-02-24T12:00:18-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '81c76525-cdca-4eb4-96d4-bdb656cdcd83'	System	03 Mar 2021 20:33:38
User entered '24 Feb 2021 17:00:18'	System	03 Mar 2021 20:33:38

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-03T15:33:44-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '27fe9e36-1f00-4011-b765-351683a6a11b' User entered 'No (N)'	System	03 Mar 2021 20:33:50
	System	03 Mar 2021 20:33:50

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-03T15:33:45-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '27fe9e36-1f00-4011-b765-351683a6a11b'	System	03 Mar 2021 20:33:50
User entered 'No (N)'	System	03 Mar 2021 20:33:50

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-03T15:33:47-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '27fe9e36-1f00-4011-b765-351683a6a11b' User entered '03 Mar 2021 20:33:47'	System	03 Mar 2021 20:33:50
	System	03 Mar 2021 20:33:50

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-11T20:18:53-06:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '831cbe4f-71a9-4379-b36d-412c0a6a172f'	System	12 Mar 2021 02:21:51
User entered 'No (N)'	System	12 Mar 2021 02:21:51

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-11T20:18:55-06:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '831cbe4f-71a9-4379-b36d-412c0a6a172f'	System	12 Mar 2021 02:21:51
User entered 'No (N)'	System	12 Mar 2021 02:21:51

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-11T20:18:57-06:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '831cbe4f-71a9-4379-b36d-412c0a6a172f'	System	12 Mar 2021 02:21:51
User entered '11 Mar 2021 20:18:57'	System	12 Mar 2021 02:21:51

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-15T16:34:40-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7c2ebb75-33be-4a62-92a0-f7966a893646' User entered 'No (N)'	System	15 Mar 2021 21:34:45
	System	15 Mar 2021 21:34:45

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-15T16:34:41-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7c2ebb75-33be-4a62-92a0-f7966a893646'	System	15 Mar 2021 21:34:45
User entered 'No (N)'	System	15 Mar 2021 21:34:45

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-15T16:34:43-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7c2ebb75-33be-4a62-92a0-f7966a893646' User entered '15 Mar 2021 16:34:43'	System	15 Mar 2021 21:34:45
	System	15 Mar 2021 21:34:45

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-24T16:17:41-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '53209b35-bc20-45e4-b6f5-a30a9b52bfcf'	System	24 Mar 2021 21:17:49
User entered 'No (N)'	System	24 Mar 2021 21:17:49

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-24T16:17:42-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '53209b35-bc20-45e4-b6f5-a30a9b52bfcf'	System	24 Mar 2021 21:17:49
User entered 'No (N)'	System	24 Mar 2021 21:17:49

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-24T16:17:44-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '53209b35-bc20-45e4-b6f5-a30a9b52bfcf' User entered '24 Mar 2021 16:17:44'	System	24 Mar 2021 21:17:49
	System	24 Mar 2021 21:17:49

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-01T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f3b7b2-82d6-4ed3-9d7e-ef01b79f91ae'	System	01 Apr 2021 21:59:31
User entered 'No (N)'	System	01 Apr 2021 21:59:31

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-01T17:59:24-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f3b7b2-82d6-4ed3-9d7e-ef01b79f91ae'	System	01 Apr 2021 21:59:31
User entered 'No (N)'	System	01 Apr 2021 21:59:31

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-01T17:59:27-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '65f3b7b2-82d6-4ed3-9d7e-ef01b79f91ae'	System	01 Apr 2021 21:59:31
User entered '01 Apr 2021 17:59:27'	System	01 Apr 2021 21:59:31

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-07T15:25:08-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c36f481c-247b-4931-bd83-f7b0e1b63214'	System	07 Apr 2021 19:25:15
User entered 'No (N)'	System	07 Apr 2021 19:25:15

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-07T15:25:09-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c36f481c-247b-4931-bd83-f7b0e1b63214'	System	07 Apr 2021 19:25:15
User entered 'No (N)'	System	07 Apr 2021 19:25:15

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-07T15:25:11-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c36f481c-247b-4931-bd83-f7b0e1b63214'	System	07 Apr 2021 19:25:15
User entered '07 Apr 2021 15:25:11'	System	07 Apr 2021 19:25:15

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-16T12:05:05-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '55f6061d-c923-46d3-af26-16ad1ce3c3ca' User entered 'No (N)'	System	16 Apr 2021 17:09:17
	System	16 Apr 2021 17:09:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-16T12:05:07-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '55f6061d-c923-46d3-af26-16ad1ce3c3ca' User entered 'No (N)'	System	16 Apr 2021 17:09:17
	System	16 Apr 2021 17:09:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-16T12:05:12-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '55f6061d-c923-46d3-af26-16ad1ce3c3ca'	System	16 Apr 2021 17:09:17
User entered '16 Apr 2021 12:05:12'	System	16 Apr 2021 17:09:17

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-22T17:59:16-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7dc08bdb-007c-461b-997c-7c4df028d0c6'	System	22 Apr 2021 23:02:57
User entered 'No (N)'	System	22 Apr 2021 23:02:57

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-22T17:59:18-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7dc08bdb-007c-461b-997c-7c4df028d0c6'	System	22 Apr 2021 23:02:57
User entered 'No (N)'	System	22 Apr 2021 23:02:57

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-22T17:59:21-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '7dc08bdb-007c-461b-997c-7c4df028d0c6'	System	22 Apr 2021 23:02:57
User entered '22 Apr 2021 17:59:21'	System	22 Apr 2021 23:02:57

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-28T13:19:40-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c8aa711d-8b9f-47a6-bbb3-5597f61d46b3'	System	28 Apr 2021 21:37:36
User entered 'No (N)'	System	28 Apr 2021 21:37:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

Have you been exposed to someone with 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 (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-28T13:19:43-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c8aa711d-8b9f-47a6-bbb3-5597f61d46b3'	System	28 Apr 2021 21:37:36
User entered 'No (N)'	System	28 Apr 2021 21:37:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-04-28T13:19:52-04:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: 'c8aa711d-8b9f-47a6-bbb3-5597f61d46b3' User entered '28 Apr 2021 13:19:52'	System	28 Apr 2021 21:37:36
	System	28 Apr 2021 21:37:36

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '28 Nov 2022 00:01'	System	20 Nov 2020 10:57:24

US3992037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:41:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:24
Amendment Manager: User entered '02 Dec 2022 23:59'	System	20 Nov 2020 10:57:24

US3992037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:41:11

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)	26 Apr 2021 05:33:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-03T15:33:38-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '90538893-0f35-4e0c-a026-07fd59ca5b73'	System	03 Mar 2021 20:33:43
User entered 'No (N)'	System	03 Mar 2021 20:33:43

US3992037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:41:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:33:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC68B6A4-DD05-4DAB-93AC-941C2114AECD)', Time: '2021-03-03T15:33:41-05:00', User OID: 'PatientReportedOutcome (US3992037)', ODM File OID: '90538893-0f35-4e0c-a026-07fd59ca5b73'	System	03 Mar 2021 20:33:43
User entered '03 Mar 2021 20:33:41'	System	03 Mar 2021 20:33:43

US3992037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:07

US3992037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Jan 2021 20:11:23
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	29 Jan 2021 20:11:23
User entered '26 Dec 2020' reason for change: Data Entry Error	Karen Cornelius (b) (4)	29 Jan 2021 20:11:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Jan 2021 20:11:07
User entered '26 Dec 2021'	System	29 Jan 2021 20:11:07
	Karen Cornelius (b) (4)	29 Jan 2021 20:11:07
	(b) (4)	

US3992037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:07

US3992037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:07
	(b) (4)	

US3992037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:31

US3992037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:17:16
User entered 'I'	System	29 Jan 2021 20:11:31

US3992037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:51

US3992037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '28 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:51

US3992037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:51

US3992037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:11:51
	(b) (4)	

US3992037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	29 Jan 2021 20:12:04

US3992037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User entered 'I'	System	29 Jan 2021 20:12:04

US3992037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:41:22
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	26 Feb 2021 13:35:32

US3992037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:41:22
User entered '25 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	26 Feb 2021 13:35:32

US3992037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:41:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	26 Feb 2021 13:35:32

US3992037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:41:22
User entered empty.	(b) (4) Karen Cornelius (b) (4)	26 Feb 2021 13:35:32

US3992037

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:41:22
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	26 Feb 2021 13:35:17

US3992037

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User entered 'I'	System	26 Feb 2021 13:35:17

US3992037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	30 Mar 2021 15:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:48:48

US3992037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	30 Mar 2021 15:06:34
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:48:48

US3992037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	30 Mar 2021 15:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:48:48

US3992037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	30 Mar 2021 15:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:48:48

US3992037

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User signature succeeded.	Kathleen Mullane (b) (4)	30 Mar 2021 15:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:49:04

US3992037

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 07:01:36
User entered 'I'	System	29 Mar 2021 18:49:04

US3992037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:22:36

US3992037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:22:36

US3992037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:22:36

US3992037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	28 Apr 2021 15:22:36

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:24:10

US3992037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:25:14

US3992037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:25:14

US3992037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:26:00

US3992037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:26:00

US3992037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered '14:25'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:26:00

US3992037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 14:25'	System	28 Apr 2021 15:26:00

US3992037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	29 Apr 2021 15:07:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:26:14

US3992037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:26:14

US3992037

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

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:30

US3992037

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

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:30

US3992037

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

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)'	Karen Cornelius (b) (4)	08 Jan 2021 15:51:30

US3992037

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

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 15:51:30

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:02:01

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:02:01

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Placebo (Placebo)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:37:43
User entered 'Placebo (Placebo)'	Karen Cornelius (b) (4)	08 Jan 2021 15:51:50
	(b) (4)	

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:37:43
User entered 'Placebo (Placebo)'	Karen Cornelius (b) (4)	08 Jan 2021 15:51:50
	(b) (4)	

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '1'	System	08 Jan 2021 15:51:50

US3992037

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

Form: Unblinding

Generated On: 10 Jun 2021 10:41:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'I'	System	08 Jan 2021 15:51:50

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '165.1' cm	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '56.7' kg	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '20.80123'	System	08 Jan 2021 15:54:15
DataPoint set to visible.	System	08 Jan 2021 15:51:50

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '165.1' cm	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '56.7' kg	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '20.80123'	System	08 Jan 2021 15:54:15
DataPoint set to visible.	System	08 Jan 2021 15:51:50

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:21'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '06 Jan 2021 13:21'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '36.9' C	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '87'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'bpm'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '18'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'breaths/min'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '120'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '66'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '165.1' cm	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '56.7' kg	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:41:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '20.80123'	System	08 Jan 2021 15:54:15
DataPoint set to visible.	System	08 Jan 2021 15:51:50

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14:20'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '06 Jan 2021 14:20'	System	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '37.7' C	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '83'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'bpm'	System	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'breaths/min'	System	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '119'	Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '67'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	08 Jan 2021 15:54:15

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:27

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:27

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mRNA-1273'	System	08 Jan 2021 15:52:28
DataPoint set to visible.	System	08 Jan 2021 15:51:50

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:50'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '06 Jan 2021 13:50'	System	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'ONCE'	System	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 15:52:28

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:49

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 06JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Visit 3 Day 57 visit in EDC and PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 06JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Visit 3 Day 57 visit in EDC and PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you ' answered with 'OL-D1 and D57 drawn on same day. Samples sent.' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 06JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Visit 3 Day 57 visit in EDC and PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you ' (Site from DM). User entered '06 Jan 2021'	(b) (4), (b) (6) Karen Cornelius (b) (4) (b) (4) (b) (4), (b) (6)	11 Feb 2021 11:40:14 09 Feb 2021 17:34:04 03 Feb 2021 18:09:23 08 Jan 2021 15:54:49

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:25'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:54:49

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '06 Jan 2021 13:25'	System	08 Jan 2021 15:54:49

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:55:08

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '06 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:55:08

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:41:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:27'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:55:08

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:41:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '06 Jan 2021 13:27'	System	08 Jan 2021 15:55:08

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Jan 2021 15:55:27

US3992037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'I'	System	08 Jan 2021 15:55:27

US3992037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	15 Jan 2021 12:40:32

US3992037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	15 Jan 2021 12:40:32

US3992037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	15 Jan 2021 12:40:32

US3992037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	15 Jan 2021 12:40:32

US3992037

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	15 Jan 2021 12:40:16

US3992037

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'I'	System	15 Jan 2021 12:40:16

US3992037

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '1'	System	15 Jan 2021 12:40:16
DataPoint set to visible.	System	15 Jan 2021 12:40:16

US3992037

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:22:23

US3992037

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '05 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:22:23

US3992037

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Clinic (Clinic)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:22:23

US3992037

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'OLD29'	System	07 Feb 2021 15:22:23

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '05 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '13:46'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '05 Feb 2021 13:46'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '36.0' C	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '91'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'bpm'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'breaths/min'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '117'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '67'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '05 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14:45'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '05 Feb 2021 14:45'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '36.6' C	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '84'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'bpm'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'breaths/min'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '121'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '65'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	07 Feb 2021 15:23:48

US3992037

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:03

US3992037

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '05 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:03

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mRNA-1273'	System	07 Feb 2021 15:24:24
DataPoint set to visible.	System	15 Jan 2021 12:40:16

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '05 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14:15'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '05 Feb 2021 14:15'	System	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'ONCE'	System	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:41:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'INTRAMUSCULAR'	System	07 Feb 2021 15:24:24

US3992037

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	07 Feb 2021 15:24:32

US3992037

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'I'	System	07 Feb 2021 15:24:32

US3992037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Feb 2021 14:55:49

US3992037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '12 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	17 Feb 2021 14:55:49

US3992037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	17 Feb 2021 14:55:49

US3992037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:41:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	Karen Cornelius (b) (4)	17 Feb 2021 14:55:49

US3992037

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Feb 2021 14:55:55

US3992037

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:41:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'I'	System	17 Feb 2021 14:55:55

US3992037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:57:13

US3992037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '09 Mar 2021'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:57:13

US3992037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[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 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Clinic (Clinic)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:57:13

US3992037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:41:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'OLD57'	System	10 Mar 2021 15:57:13

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '09 Mar 2021'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20
	(b) (4)	

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '11:05'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '09 Mar 2021 11:05'	System	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:23
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Karen Cornelius (b) (4) (b) (4)	10 Mar 2021 15:58:28
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Mar 2021 15:58:20
User entered '35.7' C	Karen Cornelius (b) (4) (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '89'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'bpm'	System	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '16'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'breaths/min'	System	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '114'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '70'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered 'mmHg'	System	10 Mar 2021 15:58:20

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50

US3992037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50

US3992037

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:52

US3992037

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '09 Mar 2021'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:58:52

US3992037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:59:25

US3992037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '09 Mar 2021'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:59:25
	(b) (4)	

US3992037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
User entered '11:10'	(b) (4) Karen Cornelius (b) (4)	10 Mar 2021 15:59:25

US3992037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:41:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:32:50
User entered '09 Mar 2021 11:10'	System	10 Mar 2021 15:59:25

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:43
User entered '13 Jan 2021'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:17
	(b) (4)	

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:43
User entered 'I'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:17
	(b) (4)	

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Feb 2021 21:01:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:43
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:17

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:43
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:17
	(b) (4)	

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:43
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:17
	(b) (4)	

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:58
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:54
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:43
	(b) (4)	

US3992037

Folder: Unscheduled 13 Jan 2021

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:07:58
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 21:01:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 17:35:54
User entered '13 Jan 2021'	Jill Stetkevych (b) (4)	15 Jan 2021 20:10:43
	(b) (4)	

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 13:54:05
User entered '14 Jan 2021' reason for change: Data Entry Error	System	27 Jan 2021 13:54:05
User opened query 'Data is required. Please complete.' (Site from System).	Karen Cornelius (b) (4)	27 Jan 2021 13:54:05
User entered empty.	(b) (4)	
	System	15 Jan 2021 20:03:38
	Jill Stetkevych (b) (4)	15 Jan 2021 20:03:38
	(b) (4)	

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:03:38

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'I'	Jill Stetkevych (b) (4)	15 Jan 2021 20:03:38

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:03:38

US3992037

Folder: **Unscheduled 14 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 10:41:11**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:03:38

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14 Jan 2021'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '08:15' reason for change: Data Entry Error	Jill Stetkevych (b) (4)	15 Jan 2021 20:06:28
User entered '12:07'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User entered '14 Jan 2021 08:15'	System	15 Jan 2021 20:06:28
User entered '14 Jan 2021 12:07'	System	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '97.6' F	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Other (Other)'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'unknown'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '75'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User entered 'bpm'	System	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User entered 'breaths/min'	System	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '126'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User entered 'mmHg'	System	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '76'	Jill Stetkevych (b) (4)	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08
User entered 'mmHg'	System	15 Jan 2021 20:05:17

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Vital Signs

Generated On: 10 Jun 2021 10:41:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:54:08

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14 Jan 2021'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:24

US3992037

Folder: **Unscheduled 14 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 10:41:11**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'I'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:24

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:24

US3992037

Folder: **Unscheduled 14 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 10:41:11**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:24

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:41:11

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:02
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '0'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:24

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:06
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:42

US3992037

Folder: Unscheduled 14 Jan 2021

Form: Physical Examination

Generated On: 10 Jun 2021 10:41:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:08:06
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '14 Jan 2021'	Jill Stetkevych (b) (4)	15 Jan 2021 20:11:42

US3992037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:41:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:31:30
User signature succeeded.	Kathleen Mullane (b) (4)	09 Apr 2021 15:40:34
User closed query 'Fo appendicitis, please change action taken to Not applicable since AE was after last dose. Thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:56:10
Query 'Fo appendicitis, please change action taken to Not applicable since AE was after last dose. Thanks' answered with 'data updated' (Site from CRA).	Karen Cornelius (b) (4) (b) (4)	17 Feb 2021 16:58:23
User opened query 'Fo appendicitis, please change action taken to Not applicable since AE was after last dose. Thanks' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 17:09:04
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:32
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:51:11

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:08:35

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User closed query 'PER MM: RE-QUERY: Per response it was reported that COVID test performed. However, Covid-19 assessment was not recorded. Please complete all necessary forms as appropriate. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 Mar 2021 19:08:07
Query 'PER MM: RE-QUERY: Per response it was reported that COVID test performed. However, Covid-19 assessment was not recorded. Please complete all necessary forms as appropriate. Thank you.' answered with 'COVID test was performed at an outside facility; the subject has been contacted again for results; will continue to follow' (Site from DM).	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:42:57
User opened query 'PER MM: RE-QUERY: Per response it was reported that COVID test performed. However, Covid-19 assessment was not recorded. Please complete all necessary forms as appropriate. Thank you.' (Site from DM).	Jill Stetkevych (b) (4) (b) (4)	24 Feb 2021 17:11:05
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:17:25
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject developed chest pain while in New York; went to a local MD and had a COVID test performed. Subject has been entering his symptoms in his e-diary. Instructed to let us know about his test results and to quarantine in place until he has been asymptomatic for 3 days. Subject was to contact us.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:15:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	16 Feb 2021 14:58:44
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:26:06
	(b) (4), (b) (6)	19 Jan 2021 21:36:45

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Pleuritic pain, LLT: Pleuritic pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 14:55:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 14:55:00
Data point term sent to Coder	System	11 Jan 2021 14:53:55
User entered 'Pleuritic Chest Pain'	Karen Cornelius (b) (4)	11 Jan 2021 14:53:28
	(b) (4)	

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '30 Dec 2020'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User entered empty.	System	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '1 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User entered empty.	System	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'l'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Karen Cornelius (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 14:53:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 14:53:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:45
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 14:53:28
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Karen Cornelius (b) (4) (b) (4)	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User entered '0'	System	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52
User entered '1'	System	11 Jan 2021 14:53:28

US3992037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:41:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:52

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:33
User entered 'USA-US219-2021-mRNA-1273-P301000002'	System	15 Jan 2021 12:25:30
User entered 'New'	(b) (4), (b) (6)	15 Jan 2021 12:25:30

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Acute appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 20:16:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 20:16:15
Data point term sent to Coder	System	15 Jan 2021 20:15:04
Coding entries removed.	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:14:54
User entered 'Acute APPENDICITIS' reason for change: New Information	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:14:54
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:59:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:59:01
Data point term sent to Coder	System	14 Jan 2021 21:58:47
User entered 'appendicitis'	Jill Stetkevych (b) (4) (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '10 Jan 2021' reason for change: Data Entry Error	Jill Stetkevych (b) (4)	15 Jan 2021 20:19:04
User entered '13 Jan 2021'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '13 Jan 2021' reason for change: Data Entry Error	Jill Stetkevych (b) (4)	15 Jan 2021 20:18:33
User entered '14 Jan 2021'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'I'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '13 Jan 2021'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '14 Jan 2021'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'No (N)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '0'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Not Related (NOT RELATED)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:05:43
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 17:16:09
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'data updated' (Site from Safety).	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:40:54
DataPoint Un-verified.	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:40:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:40:36
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:47:05
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Not Applicable (NOT APPLICABLE)'	Jill Stetkevych (b) (4) (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Karen Cornelius (b) (4)	17 Feb 2021 16:57:51
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'None (NONE)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31
	(b) (4)	

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	13 Feb 2021 14:27:14
User entered '0' reason for change: Per Query Resolution	Karen Cornelius (b) (4)	13 Feb 2021 14:27:14
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	13 Feb 2021 14:26:51
User entered '1' reason for change: Per Query Resolution	System	13 Feb 2021 14:26:51
DataPoint Un-verified.	Karen Cornelius (b) (4)	13 Feb 2021 14:26:51
DataPoint Verified.	(b) (4)	04 Feb 2021 17:06:54
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 21:36:45
	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31
	(b) (4)	

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 12:06:48
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'corrected per query ' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	13 Feb 2021 14:27:32
User entered '0' reason for change: Per Query Resolution	Karen Cornelius (b) (4) (b) (4)	13 Feb 2021 14:26:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:58:09
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered '1'	Jill Stetkevych (b) (4) (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'I'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:06:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45
User entered empty.	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:56:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:06:54
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 17:16:06
User closed query 'PV Query: Please provide subject's relevant medical history. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 17:16:02
Query 'PV Query: Please provide subject's relevant medical history. If none, please state so.' answered with 'no past meal history reported by subject' (Site from Safety).	Karen Cornelius (b) (4)	27 Jan 2021 13:43:50
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'medications updated' (Site from Safety).	Karen Cornelius (b) (4)	27 Jan 2021 13:42:12
User opened query 'PV Query: Please provide subject's relevant medical history. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:47:58
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:47:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:36:45

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT FELT UNWELL. SCAN AT URGENT AID CLINIC INDICATED APPENDICITIS. PATIENT HAD APPENDECTOMY ON 13/JAN/2021. MEDICAL RECORDS HAVE BEEN REQUESTED. MORE INFO WILL FOLLOW. Addendum: Performed CT scan Abd/pelvis, laparoscopic appendectomy was performed. Patient discharged home on 1/14/2021.'	Jill Stetkevych (b) (4)	15 Jan 2021 20:14:54
reason for change: New Information		
User entered 'Patient felt unwell. Scan at urgent aid clinic indicated appendicitis. Patient had appendectomy on 13/Jan/2021. Medical records have been requested. More info will follow.'	Jill Stetkevych (b) (4)	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 21:58:31

US3992037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:41:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 21:58:31

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:41:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:31:30
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User closed query 'A review of the discharge summary states subject was also prescribed Antibiotics, Tylenol 325, General Anesthesia, Lidocaine 2% and Marcaine 0.5% for the procedure. Please review and add all meds' (Site from CRA). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 04:17:28
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 13:02:33
Query 'A review of the discharge summary states subject was also prescribed Antibiotics, Tylenol 325, General Anesthesia, Lidocaine 2% and Marcaine 0.5% for the procedure. Please review and add all meds' answered with 'Con Medications updated; no antibiotics prescribed' (Site from CRA).	Karen Cornelius (b) (4)	27 Jan 2021 13:02:33
User opened query 'A review of the discharge summary states subject was also prescribed Antibiotics, Tylenol 325, General Anesthesia, Lidocaine 2% and Marcaine 0.5% for the procedure. Please review and add all meds' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:02:10
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 22:18:26
	(b) (4), (b) (6)	19 Jan 2021 21:36:55
	Karen Cornelius (b) (4)	27 Sep 2020 14:35:18
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:26:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:26:24
Data point term sent to Coder Coding entries removed.	System Karen Cornelius (b) (4) (b) (4)	31 Mar 2021 13:25:22 31 Mar 2021 13:24:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:34:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:34:56
Data point term sent to Coder Coding entries removed.	System Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 15:19:41 09 Mar 2021 15:18:46
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:42:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:05:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:05:03
Data point term sent to Coder User entered 'Oxycodone HCL'	System Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:04:17 27 Jan 2021 13:03:56

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 14:11:22
Query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' answered with 'indication updated per query' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	31 Mar 2021 13:25:28
User opened query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 23:30:46
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:03:56

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

Indication

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:23
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	31 Mar 2021 13:24:22
	(b) (4)	
User entered 'ABDOMINAL PAIN; OP-RELATED PAIN' reason for change: New Information	Karen Cornelius (b) (4)	31 Mar 2021 13:24:22
	(b) (4)	
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:46:37
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. answered with 'updated' (Site from DM).	Karen Cornelius (b) (4)	09 Mar 2021 15:18:58
	(b) (4)	
Signature has been broken.	Karen Cornelius (b) (4)	09 Mar 2021 15:18:46
	(b) (4)	
User entered 'ABDOMINAL PAIN prophylaxis, POST OP-RELATED PAIN prophylaxis' reason for change: New Information	Karen Cornelius (b) (4)	09 Mar 2021 15:18:46
	(b) (4)	
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:46:59
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'abdominal pain, post op-related pain'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'mg (mg)'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'as needed (PRN)'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '14 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:03:56
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:03:56

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:03:56

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:03:56

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:27:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:27:27
Data point term sent to Coder Coding entries removed.	System Karen Cornelius (b) (4)	31 Mar 2021 13:26:22 31 Mar 2021 13:26:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 15:19:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 15:19:57
Data point term sent to Coder Coding entries removed.	System Karen Cornelius (b) (4)	09 Mar 2021 15:19:41 09 Mar 2021 15:19:20
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 13:07:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 13:07:05
Data point term sent to Coder User entered 'acetaminophen'	System Karen Cornelius (b) (4)	27 Jan 2021 13:06:18 27 Jan 2021 13:05:22

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 14:11:29
Query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' answered with 'indication updated per query' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	31 Mar 2021 13:25:41
User opened query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 23:30:22
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:42:57
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:05:22

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:23
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	31 Mar 2021 13:26:07
	(b) (4)	
User entered 'ABDOMINAL PAIN, POST OP-RELATED Pain' reason for change: Per Query Resolution	Karen Cornelius (b) (4)	31 Mar 2021 13:26:07
	(b) (4)	
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:02:08
	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:46:51
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. answered with 'updated' (Site from DM).	Karen Cornelius (b) (4)	09 Mar 2021 15:19:30
	(b) (4)	
Signature has been broken.	Karen Cornelius (b) (4)	09 Mar 2021 15:19:20
	(b) (4)	
User entered 'ABDOMINAL PAIN prophylaxis, POST OP-RELATED PAIN prophylaxis' reason for change: Per Query Resolution	Karen Cornelius (b) (4)	09 Mar 2021 15:19:20
	(b) (4)	
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:47:17
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Abdominal pain, post op related pain'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '650'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'mg (mg)'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'as needed (PRN)'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '14 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:05:22
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:05:22

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:05:22

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:05:22

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Jan 2021 13:24:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:24:30
Data point term sent to Coder	System	27 Jan 2021 13:07:23
User entered 'Lidocaine'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:06:51

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:47:00
Query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' answered with 'correct as entered, this is a medication' (Site from DM).	Karen Cornelius (b) (4)	09 Mar 2021 15:22:48
User opened query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:47:31
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'pre-operative anesthesia'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'unknown'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Other (OTHER)'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '2%'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'once (ONCE)'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '13 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '13 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:06:51
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:06:51

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:06:51

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:06:51

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Jan 2021 13:24:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:24:29
Data point term sent to Coder	System	27 Jan 2021 13:08:23
User entered 'Mercaine'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:08:02

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:47:38
Query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' answered with 'correct as entered, this is a medication' (Site from DM).	Karen Cornelius (b) (4)	09 Mar 2021 15:23:14
User opened query 'Per DM CLR: Please verify if this procedure should be moved to the ConProc eCRF page. If so, update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:47:42
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'pre-operative anesthesia'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'unknown'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'Other (OTHER)'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '0.5%'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'once (ONCE)'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '13 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '13 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:08:02
	(b) (4)	

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:08:02

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:08:02

US3992037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:41:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:08:02

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:41:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:31:30
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:37:06
User entered 'Yes (Y)'	Jill Stetkevych (b) (4)	14 Jan 2021 22:00:03

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:41:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:37:21
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	15 Jan 2021 19:57:20
User entered '13 Jan 2021' reason for change: Data Entry Error	Jill Stetkevych (b) (4)	15 Jan 2021 19:57:20
	(b) (4)	
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	14 Jan 2021 22:00:27
User entered '13 Jan 2013'	Jill Stetkevych (b) (4)	14 Jan 2021 22:00:27
	(b) (4)	

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:41:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered 'Laparoscopic APPENDECTOMY'	Jill Stetkevych (b) (4)	15 Jan 2021 19:58:04
reason for change: Data Entry Error	(b) (4)	
User entered 'appendectomy'	Jill Stetkevych (b) (4)	14 Jan 2021 22:00:27
	(b) (4)	

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:41:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered 'Adverse Event (AE)'	Jill Stetkevych (b) (4)	14 Jan 2021 22:00:27
	(b) (4)	

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:41:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered empty.	Jill Stetkevych (b) (4)	14 Jan 2021 22:00:27
	(b) (4)	

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:41:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:23:53
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered '13 Jan 2021'	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:15:57

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:41:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:23:53
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered 'CT scan abdomen/pelvis'	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:15:57

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:41:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:23:53
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:37:21
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Jan 2021 20:16:23
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Jan 2021 20:15:57
User entered 'Diagnostic (DIAGNOSTIC)'	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:15:57

US3992037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:41:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:23:53
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:37:21
User entered empty; reason for change Data Entry Error	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:16:23
User entered 'acute appendicitis'	Jill Stetkevych (b) (4) (b) (4)	15 Jan 2021 20:15:57

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'USA-US219-2021-MRNA-1273-P301000002'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'USA-US219-2021-MRNA-1273-P301000002'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:41:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
User entered '15/Jan/2021 07:25'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:41:11

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.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered	System	15 Jan 2021 12:25:30
'USA-US219-2021-MRNA-1273-P301000002'		

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:41:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
User entered '19/Jan/2021 08:00'	System	19 Jan 2021 13:00:36

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:41:11

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.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:33:37
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 13:00:36

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered	System	15 Jan 2021 12:25:30
'USA-US219-2021-MRNA-1273-P301000002'		

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:41:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '28/Jan/2021 17:17'	(b) (4) System	28 Jan 2021 17:17:10

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:41:11

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.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:28:10
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 17:17:10

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered	System	15 Jan 2021 12:25:30
'USA-US219-2021-MRNA-1273-P301000002'		

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:41:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '16/Feb/2021 11:28'	(b) (4) System	16 Feb 2021 16:28:25

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:41:11

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.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 14:08:42
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 16:28:25

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered	System	15 Jan 2021 12:25:30
'USA-US219-2021-MRNA-1273-P301000002'		

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Yes (Y)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'No (N)'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Kathleen'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Mullane'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '5841 South Maryland Ave MC 5065'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'Chicago'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered 'IL'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:25:52
User entered '60637'	System	15 Jan 2021 12:25:30

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:33:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:00:26
User entered 'US'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:41:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
	(b) (4)	
User entered '5'	System	18 Feb 2021 14:09:02
User entered '4'	System	16 Feb 2021 16:28:25
User entered '3'	System	28 Jan 2021 17:17:10
User entered '2'	System	19 Jan 2021 13:00:36
User entered '1'	System	15 Jan 2021 12:26:00

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:41:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
User entered '18/Feb/2021 09:09'	(b) (4) System	18 Feb 2021 14:09:02

US3992037

Folder: SAE USA-US219-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:41:11

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.	Kathleen Mullane (b) (4)	25 Feb 2021 22:42:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 14:13:41
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 14:09:02