

US3412246 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:58

All time stamps listed in this document are displayed in GMT

US3412246

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:51:17

Generated On: 09 Jun 2021 17:34:58

Participant ID

US3412246

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

US3412246

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412246

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3412246

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3412246

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412246

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Were any significant conditions reported?

Yes ☒

No ☐

US3412246

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Condition	HYPOGONADISM/LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3412246

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:45 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:45
Height (<i>xxx.x</i>)	170.0 cm
Weight (<i>xxx.x</i>)	65.9 kg
BMI (<i>xxx.x</i>)	22.80277 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)	

US3412246

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3412246

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186361

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 ☒

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Height	ND - Not Done
Weight	ND - Not Done

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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)	14 AUG 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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)	14 AUG 2020
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:49
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412246

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

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.

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 AUG 2020

What was the treatment time? (00:00-23:59) 13:15 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 13:15

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

US3412246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	14 AUG 2020 12:57

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:53	14 AUG 2020 12:53
Nasopharyngeal Swab 2	No		

US3412246

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:31

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

96.9 °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

14 AUG 2020 13:56

PC Open Date & Time

14 AUG 2020 13:35

PC Close Date & Time

14 AUG 2020 16:05

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 14 AUG 2020 21:22

PC Open Date & Time 14 AUG 2020 17:00

PC Close Date & Time 15 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 AUG 2020 21:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

97.7 °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

16 AUG 2020 20:54

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 01:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

19 AUG 2020 20:40

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

20 AUG 2020 22:17

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

20

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

14 AUG 2020 13:57

PC Open Date & Time

14 AUG 2020 13:35

PC Close Date & Time

14 AUG 2020 16:05

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

15

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

14 AUG 2020 21:24

PC Open Date & Time

14 AUG 2020 17:00

PC Close Date & Time

15 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 21:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:54

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 20:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

19 AUG 2020 01:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:40

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 22:19

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:57
PC Open Date & Time	14 AUG 2020 13:35
PC Close Date & Time	14 AUG 2020 16:05

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 21:25
PC Open Date & Time	14 AUG 2020 17:00
PC Close Date & Time	15 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

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 ☒

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:17
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

46 of 2122

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:55
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

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 ☒

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:40
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

50 of 2122

EAB) (1725)

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 01:05
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 2122

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:41
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2122

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 22:20
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3412246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:27 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:27
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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)	11 SEP 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:46
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3412246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:10 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:10

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

US3412246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

12:40 (24 HR)

Collection date and time (derived)

11 SEP 2020 12:40

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:34	11 SEP 2020 12:34
Nasopharyngeal Swab 2	No		

US3412246

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

96.7 °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

11 SEP 2020 13:41

PC Open Date & Time

11 SEP 2020 13:30

PC Close Date & Time

11 SEP 2020 16:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 11 SEP 2020 22:27

PC Open Date & Time 11 SEP 2020 16:55

PC Close Date & Time 12 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	12 SEP 2020 21:51
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 13 SEP 2020 22:48

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 00:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 22:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:32

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

11 SEP 2020 13:43

PC Open Date & Time

11 SEP 2020 13:30

PC Close Date & Time

11 SEP 2020 16:00

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

11 SEP 2020 22:28

PC Open Date & Time

11 SEP 2020 16:55

PC Close Date & Time

12 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

12 SEP 2020 21:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

13 SEP 2020 22:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

15 SEP 2020 00:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

15 SEP 2020 22:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

16 SEP 2020 22:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:32

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 13:43
PC Open Date & Time	11 SEP 2020 13:30
PC Close Date & Time	11 SEP 2020 16:00

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:29
PC Open Date & Time	11 SEP 2020 16:55
PC Close Date & Time	12 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

90 of 2122

EAB) (1725)

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

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 ☒

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:50
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

94 of 2122

EAB) (1725)

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 00:24
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

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 ☒

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:06
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2122

EAB) (1725)

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:36
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2122

EAB) (1725)

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:33
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3412246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:12

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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) _____

US3412246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

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.

US3412246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	9 OCT 2020 11:40

US3412246

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:32

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 21:27:51

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 08:08:51

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 00:41:01

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 00:32:33

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 00:47:27

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

06 DEC 2020 01:35:32

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

14 DEC 2020 21:42:46

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

21 DEC 2020 12:05:11

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

28 DEC 2020 11:22:31

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

03 JAN 2021 09:43:41

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

11 JAN 2021 13:17:10

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

17 JAN 2021 14:39:04

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

25 JAN 2021 06:48:31

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

04 FEB 2021 14:26:47

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

08 FEB 2021 15:59:33

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

15 FEB 2021 07:59:46

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

21 FEB 2021 14:01:01

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

28 FEB 2021 11:19:13

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 MAR 2021 06:55:18
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

18 MAR 2021 14:21:27

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 <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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 07:34:20

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 13:25:50

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 20:16:51

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 14:54:42

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 MAY 2021 21:06:49
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 299

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Patient Cloud Close Date & Time	29 JUL 2021 23:59
---	-------------------

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Patient Cloud Close Date & Time	28 OCT 2021 23:59
---	-------------------

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 453

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 460

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 467

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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°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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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°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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Patient Cloud Close Date & Time	18 AUG 2022 23:59
---	-------------------

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 747

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Patient Cloud Close Date & Time	29 SEP 2022 23:59
---	-------------------

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3412246

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:58

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		28 FEB 2021 11:19:33

US3412246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:38:12

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:38:12

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3412246

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT4

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:51:21

Generated On: 09 Jun 2021 17:34:58

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) _____

US3412246

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

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.

US3412246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3412246

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:20

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412246

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412246

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:34:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412246

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

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

Visit date (dd MMM yyyy)	11 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
------------	---------------

US3412246

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

Date of updated informed consent (*dd MMM yyyy*) 11 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3412246

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:37 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 JAN 2021 13:37
------------------------------------	-------------------

US3412246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:51:17

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	13:38
Collection Date and Time (derived)	11 JAN 2021 13:38

US3412246

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:37:39

Generated On: 09 Jun 2021 17:34:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

AEID	USA-US061-2021-MRNA-1273-P30 1000013
Adverse event	ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6
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)	2 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 type="radio"/> Grade 4 <input checked="" 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)	2 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	04 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	321 of 2122

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

THE SUBJECT WAS CALLED
FOR A STUDY VISIT ON
05-MAR-2021 AND INDICATED
HOSPITALIZATION FOR REAR
END MVA COLLISION IN WHICH
CERVICAL SPONDYLOSIS WAS
SUSTAINED WITH RESULTANT
NECK PAIN.

SUBJECT PRESENT TO ED AS A
70 Y/O MALE WITH H/O OF
GLAUCOMA, INSOMNIA, AND
HYPOGONADISM WITH ONSET
OF UPPER EXTREMITY PAIN
FOLLOWING A MVA ON
02MAR2021. RECEIVED
BLINDED MRNA-1273 ON
14AUG2020 AND 11SEP2020.
NONSMOKER. INITIAL
PRESENTATION - STABLE VS,
PE NORMAL WITH SUBJECT
COMPLAINTS OF INCREASING
UPPER EXTREMITY PAIN.
SUBJECT WAS ADMITTED TO
ICU FOR NEURO CHECK, LABS,
AND STUDIES: CBC, CHEM
PANEL, URINE, TOXICOLOGY
SCREEN (NEGATIVE), COVID
NP/OP SWAB RAPID SCREEN -
NEGATIVE. IMAGING: CT HEAD,
NECK, CHEST,
ABDOMEN/PELVIS: CERVICAL
SPONDYLOSIS C3/C4, MRI
CERVICAL SPINE 02MAR2021 -
ANTERIOR OSTEOPHYTE

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

AVULSION FXR C6, MILD CORD
EDEMA REPRESENTING SPINAL
CORD CONTUSION, XRAY
AP/LET CERVICAL SPINE - C6
OCCLUSION FXR. TREATED
WITH OXYCODONE, IV
FENTANYL, IV
HYDROMORPHINE,
ACETAMINOPHEN,
DOCUSATE-SENNA.
DISCHARGED ON 04 MAR2021
STABLE WITH INSTRUCTION
TO WEAR ASPEN COLLAR,
CONTINUED CURRENT MEDS
AND ADDED ACETAMINOPHEN,
GABAPENTINE, OXYCODONE,
DOCUSATE-SENNA, AND
FOLLOW-UP WITH
NEUROSURGERY IN 1 WEEK.

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)	1

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

AEID	
Adverse event	CERVICAL SPONDYLOSIS C4/C4
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)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

SUBJECT PRESENT TO ED AS A
70 Y/O MALE WITH H/O OF
CLAUGCOMOA, INSOMNIA,
AND HYPOGONADISM WITH
ONSET OF UPPER EXTREMITY
PAIN FOLLOWING A MVA ON
02MAR2021. RECEIVED
BLINDED MRNA-1273 ON
14AUG2020 AND 11SEP2020.
NONSMOKER. INITIAL
PRESENTATION - STABLE VS,
PE NORMAL WITH SUBJECT
COMPLAINTS OF INCREASING
UPPER EXTREMITY PAIN.
SUBJECT WAS ADMITTED TO
ICU FOR NEURO CHECK, LABS,
AND STUDIES: CBC, CHEM
PANEL, URINE, TOXICOLOGY
SCREEN (NEGATIVE), COVID
NP/OP SWAB RAPID SCREEN -
NEGATIVE. IMAGING: CT HEAD,
NECK, CHEST,
ABDOMEN/PELVIS: CERVICAL
SPONDYLOSIS C3/C4, MRI
CERVICAL SPINE 02MAR2021 -
ANTERIOR OSTEOPHYTE
AVULSION FXR C6, MILD CORD
EDEMA REPRESENTING SPINAL
CORD CONTUSION, XRAY
AP/LET CERVICAL SPINE - C6
OCCLUSION FXR. TREATED
WITH OXYCODONE, IV
FENTANYL, IV
HYDROMORPHINE,
ACETAMINOPHEN,

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

DOCUSATE-SENNA.
DISCHARGED ON 04 MAR2021
STABLE WITH INSTRUCTION
TO WEAR ASPEN COLLAR,
CONTINUED CURRENT MEDS
AND ADDED ACETAMINOPHEN,
GABAPENTINE, OXYCODONE,
DOCUSATE-SENNA, AND
FOLLOW-UP WITH
NEUROSURGERY IN 1 WEEK.

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)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

AEID	
Adverse event	SPINAL CORD CONTUSION
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)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

SUBJECT PRESENT TO ED AS A
70 Y/O MALE WITH H/O OF
CLAUGCOMOA, INSOMNIA,
AND HYPOGONADISM WITH
ONSET OF UPPER EXTREMITY
PAIN FOLLOWING A MVA ON
02MAR2021. RECEIVED
BLINDED MRNA-1273 ON
14AUG2020 AND 11SEP2020.
NONSMOKER. INITIAL
PRESENTATION - STABLE VS,
PE NORMAL WITH SUBJECT
COMPLAINTS OF INCREASING
UPPER EXTREMITY PAIN.
SUBJECT WAS ADMITTED TO
ICU FOR NEURO CHECK, LABS,
AND STUDIES: CBC, CHEM
PANEL, URINE, TOXICOLOGY
SCREEN (NEGATIVE), COVID
NP/OP SWAB RAPID SCREEN -
NEGATIVE. IMAGING: CT HEAD,
NECK, CHEST,
ABDOMEN/PELVIS: CERVICAL
SPONDYLOSIS C3/C4, MRI
CERVICAL SPINE 02MAR2021 -
ANTERIOR OSTEOPHYTE
AVULSION FXR C6, MILD CORD
EDEMA REPRESENTING SPINAL
CORD CONTUSION, XRAY
AP/LET CERVICAL SPINE - C6
OCCLUSION FXR. TREATED
WITH OXYCODONE, IV
FENTANYL, IV
HYDROMORPHINE,
ACETAMINOPHEN,

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

DOCUSATE-SENNA.
DISCHARGED ON 04 MAR2021
STABLE WITH INSTRUCTION
TO WEAR ASPEN COLLAR,
CONTINUED CURRENT MEDS
AND ADDED ACETAMINOPHEN,
GABAPENTINE, OXYCODONE,
DOCUSATE-SENNA, AND
FOLLOW-UP WITH
NEUROSURGERY IN 1 WEEK.

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)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:41:21

Generated On: 09 Jun 2021 17:34:58

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

Yes ☒

No ☐

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

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

334 of 2122

EAB) (1725)

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

336 of 2122

EAB) (1725)

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication HYPOGONADISM / LOW
TESTOSTERONE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

BI-WEEKLY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication LUMIGAN (0.01%)

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP PER EYE

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

340 of 2122

EAB) (1725)

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication STUDY RELATED INJECTION PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 AUG 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	INFLUENZA PROPLYXIS
------------	---------------------

Dose per administration	0.5
-------------------------	-----

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CERVICAL SPONDYLOSIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2122

EAB) (1725)

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication IV FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 100

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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 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)	02 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication IV FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 100

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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 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)	02 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication IV FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 50

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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 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)	02 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication IV HYDROMORPHINE

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 0.5

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

SUBJECT RECEIVED 3 DOSES AS
NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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 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)	02 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 1000

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

EVERY 8 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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)	02 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication DOCUSATE-SENNA

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

Dose per administration 50/8.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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)		02 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication ANTERIOR OSTEOPHYTE
AVULSIAN FRACTURE C6

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

EVERY 6 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:32:00

Generated On: 09 Jun 2021 17:34:58

	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)		03 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 13:32:01

Generated On: 09 Jun 2021 17:34:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 13:32:01

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 MAR 2021	WEAR ASPEN COLLAR	Adverse Event	
03 MAR 2021	XR SPINE CERVICAL AP AND LATERAL	Adverse Event	
02 MAR 2021	CT HEAD W/O IV CONTRAST	Adverse Event	
02 MAR 2021	CT TRAUMA CTA NECK/CERVICAL SPINE	Adverse Event	
02 MAR 2021	CT CHEST W/ IV CONTRAST	Adverse Event	
02 MAR 2021	CT ABD/PELVIS W/IV CONTRAST DUAL/TRIPLE PHASE	Adverse Event	
02 MAR 2021	POC US FAST ABDOMINAL	Adverse Event	
02 MAR 2021	MRI CERVICAL SPINE WITHOUT CONTRAST	Adverse Event	

US3412246

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:58

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

US3412246

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US061-2021-MRNA-1273-P301000013
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US061-2021-MRNA-1273-P301000013
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/MAR/2021 17:18
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

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US061-2021-MRNA-1273-P301000013
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:31
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

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US061-2021-MRNA-1273-P301000013
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 11:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:51:19

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US061-2021-MRNA-1273-P301000013
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 12:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412246 (Prod: New Horizons Clinical Research)

US3412246

Form: Participant Creation

Generated On: 09 Jun 2021 17:34:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:17
User entered 'US3412246'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:24:27

US3412246

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:05

US3412246

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:24:28

US3412246

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:05

US3412246

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'SCRN'	System	14 Aug 2020 17:14:05

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:24:29

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '70'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'YEARS'	System	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '70'	System	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:35

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'Aug 2020'	System	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '2020'	System	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:27

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:24:28

US3412246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'I'	System	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:09

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User closed query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:59:06
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:29:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:29:31
Data point term sent to Coder	System	15 Oct 2020 20:27:27
Query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'LEFT EYE' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:26:54
Coding entries removed.	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:26:45
User entered 'GLAUCOMA- LEFT EYE' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:26:45
User opened query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:38:13
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:33:21

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 19:31:56
User entered 'GLAUCOMA'	(b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'UN Mar 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'Mar 2020'	System	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '2020'	System	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:31:35

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:33:21
Data point term sent to Coder	System	20 Aug 2020 19:31:56
User entered 'INSOMNIA'	(b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'Jan 2010'	System	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '2010'	System	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:31:50

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User coded data point as SOC: Endocrine disorders, HLG: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 05:48:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 05:48:39
Data point term sent to Coder	System	20 Aug 2020 19:32:56
User entered 'HYPOGONADISM/LOW TESTOSTERONE'	(b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'Jan 2000'	System	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '2000'	System	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	20 Aug 2020 19:32:15

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:45'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '14 Aug 2020 12:45'	System	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '170.0' cm	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39
DataPoint set to visible.	System	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '65.9' kg	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39
DataPoint set to visible.	System	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
Amendment Manager: User entered '22.80277'	System	16 Sep 2020 23:57:22
User entered '22.8'	System	20 Aug 2020 19:41:39
DataPoint set to visible.	System	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'kg/m2'	System	20 Aug 2020 19:41:39
DataPoint set to visible.	System	14 Aug 2020 17:15:38

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 09:03:15
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).		20 Aug 2020 19:41:44
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:41:39
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'bpm'	System	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'breaths/min'	System	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'mmHg'	System	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'mmHg'	System	20 Aug 2020 19:41:39

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47

US3412246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47

US3412246

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:55

US3412246

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:44:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:09:33
User entered '14 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 19:41:55

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:10

US3412246

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:21

US3412246

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:21

US3412246

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:21

US3412246

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'VISIT1'	System	14 Aug 2020 17:16:21

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 17:09:22

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:34:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:34:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 17:09:22
User entered '186361' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 17:09:22

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 17:09:22

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:40

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:40

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:40

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:40

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:40

US3412246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 17:01:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:18:53

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:45'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered '14 Aug 2020 12:45'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '66'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'bpm'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'breaths/min'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '118'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'mmHg'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '76'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'mmHg'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:34:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:44:00
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 19:43:48
User entered '13:49'	(b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered '14 Aug 2020 13:49'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '68'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'bpm'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'breaths/min'	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 17:01:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Sep 2020 17:01:31
User entered '120' reason for change: Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 17:01:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 19:43:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'mmHg'	System	24 Sep 2020 17:01:31
User entered empty.	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 17:01:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Sep 2020 17:01:31
User entered '80' reason for change: Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 17:01:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 19:43:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'mmHg'	System	24 Sep 2020 17:01:31
User entered empty.	System	20 Aug 2020 19:43:48

US3412246

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:08

US3412246

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:08

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	24 Sep 2020 17:17:13
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	24 Sep 2020 17:17:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 17:17:13
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	14 Aug 2020 17:18:15
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	24 Sep 2020 17:17:13
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Aug 2020 17:18:15
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 17:17:13
User entered empty.	System	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '13:15'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'ONCE'	System	24 Sep 2020 17:17:13
User entered empty.	System	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 17:17:13
User entered empty.	System	14 Aug 2020 17:18:15

US3412246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:23

US3412246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:23

US3412246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:57'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:23

US3412246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered '14 Aug 2020 12:57'	System	20 Aug 2020 19:44:23

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:53'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered '14 Aug 2020 12:53'	System	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered empty.	System	20 Aug 2020 19:44:44

US3412246

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:44:48

US3412246

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	20 Aug 2020 19:44:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:55:45', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ec9bb55b-7af6-4497-ac42-fe24d6c4dff9'	System	14 Aug 2020 17:56:18
User entered 'Yes (Y)'	System	14 Aug 2020 17:56:18

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:55:59', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ec9bb55b-7af6-4497-ac42-fe24d6c4dff9'	System	14 Aug 2020 17:56:18
User entered '96.9'	System	14 Aug 2020 17:56:18

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ec9bb55b-7af6-4497-ac42-fe24d6c4dff9'	System	14 Aug 2020 17:56:18
User entered 'No (N)'	System	14 Aug 2020 17:56:18

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ec9bb55b-7af6-4497-ac42-fe24d6c4dff9'	System	14 Aug 2020 17:56:18
User entered '14 Aug 2020 13:56'	System	14 Aug 2020 17:56:18

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 13:35'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 16:05'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:21:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered 'Yes (Y)'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:22:04', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered '98.6'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:22:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered 'Yes (Y)'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient was contacted. ' (Site from System).		16 Oct 2020 12:51:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jacob sekinger (b) (4)	08 Oct 2020 19:46:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:22:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered '1'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:22:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered '0'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:22:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fe143cd3-d3e3-4bf3-b11c-a33996d6b60a'	System	15 Aug 2020 01:22:48
User entered '14 Aug 2020 21:22'	System	15 Aug 2020 01:22:48

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 17:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 2'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	System	16 Aug 2020 01:15:35
User entered 'Yes (Y)'	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	System	16 Aug 2020 01:15:35
User entered '98.3'	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:17', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	System	16 Aug 2020 01:15:35
User entered 'Yes (Y)'	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient was contacted. ' (Site from System).	(b) (4)	16 Oct 2020 12:51:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jacob sekinger (b) (4)	08 Oct 2020 19:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	(b) (4)	
User entered '1'	System	16 Aug 2020 01:15:35
	System	16 Aug 2020 01:15:35
	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	System	16 Aug 2020 01:15:35
User entered '0'	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'c6bdf1bf-abf3-4226-b7e2-9c2de2f072ba'	System	16 Aug 2020 01:15:35
User entered '15 Aug 2020 21:15'	System	16 Aug 2020 01:15:35

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 3'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:07', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1728e389-dceb-4064-bb7b-493ef74964e9'	System	17 Aug 2020 00:54:29
User entered 'Yes (Y)'	System	17 Aug 2020 00:54:29

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1728e389-dceb-4064-bb7b-493ef74964e9'	System	17 Aug 2020 00:54:29
User entered '97.7'	System	17 Aug 2020 00:54:29

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1728e389-dceb-4064-bb7b-493ef74964e9'	System	17 Aug 2020 00:54:29
User entered 'No (N)'	System	17 Aug 2020 00:54:29

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1728e389-dceb-4064-bb7b-493ef74964e9'	System	17 Aug 2020 00:54:29
User entered '16 Aug 2020 20:54'	System	17 Aug 2020 00:54:29

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 4'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:38:37', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '65e53469-01d0-4d3c-b457-b73c844fb0e9'	System	18 Aug 2020 00:39:15
User entered 'Yes (Y)'	System	18 Aug 2020 00:39:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:38:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '65e53469-01d0-4d3c-b457-b73c844fb0e9'	System	18 Aug 2020 00:39:15
User entered '98.4'	System	18 Aug 2020 00:39:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '65e53469-01d0-4d3c-b457-b73c844fb0e9'	System	18 Aug 2020 00:39:15
User entered 'No (N)'	System	18 Aug 2020 00:39:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:13', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '65e53469-01d0-4d3c-b457-b73c844fb0e9'	System	18 Aug 2020 00:39:15
User entered '17 Aug 2020 20:39'	System	18 Aug 2020 00:39:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 5'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '976b3eeb-1faf-4e49-bdb0-e736d019deb2'	System	19 Aug 2020 05:04:37
User entered 'Yes (Y)'	System	19 Aug 2020 05:04:37

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:24', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '976b3eeb-1faf-4e49-bdb0-e736d019deb2'	System	19 Aug 2020 05:04:37
User entered '96.8'	System	19 Aug 2020 05:04:37

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '976b3eeb-1faf-4e49-bdb0-e736d019deb2'	System	19 Aug 2020 05:04:37
User entered 'No (N)'	System	19 Aug 2020 05:04:37

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '976b3eeb-1faf-4e49-bdb0-e736d019deb2'	System	19 Aug 2020 05:04:37
User entered '19 Aug 2020 01:04'	System	19 Aug 2020 05:04:37

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 6'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:09', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2070dbbc-4bbf-409c-801e-9aede1c36cb7'	System	20 Aug 2020 00:40:30
User entered 'Yes (Y)'	System	20 Aug 2020 00:40:30

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2070dbbc-4bbf-409c-801e-9aede1c36cb7'	System	20 Aug 2020 00:40:30
User entered '98.2'	System	20 Aug 2020 00:40:30

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2070dbbc-4bbf-409c-801e-9aede1c36cb7'	System	20 Aug 2020 00:40:30
User entered 'No (N)'	System	20 Aug 2020 00:40:30

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:27', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2070dbbc-4bbf-409c-801e-9aede1c36cb7'	System	20 Aug 2020 00:40:30
User entered '19 Aug 2020 20:40'	System	20 Aug 2020 00:40:30

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 7'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:14:57', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ce9c1f54-9738-45cb-85ec-cbbb9b4ad7e6'	System	21 Aug 2020 02:17:57
User entered 'Yes (Y)'	System	21 Aug 2020 02:17:57

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:15:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ce9c1f54-9738-45cb-85ec-cbbb9b4ad7e6'	System	21 Aug 2020 02:17:57
User entered '97.5'	System	21 Aug 2020 02:17:57

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:17:47', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ce9c1f54-9738-45cb-85ec-cbbb9b4ad7e6'	System	21 Aug 2020 02:17:57
User entered 'No (N)'	System	21 Aug 2020 02:17:57

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:17:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ce9c1f54-9738-45cb-85ec-cbbb9b4ad7e6'	System	21 Aug 2020 02:17:57
User entered '20 Aug 2020 22:17'	System	21 Aug 2020 02:17:57

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:30', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered 'None (1)'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:36', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered 'No (N)'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered 'Yes (Y)'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:56:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered '20'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered 'None (1)'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:16', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97294cf7-02c6-494c-8c92-3a2e9c535938'	System	14 Aug 2020 17:57:19
User entered '14 Aug 2020 13:57'	System	14 Aug 2020 17:57:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 13:35'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 16:05'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:23:21', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:23:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered 'No (N)'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:23:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered 'Yes (Y)'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:23:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered '15'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:23:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered 'None (1)'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:13', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f2c132e-0708-42c6-bbfb-bef400b63b9b'	System	15 Aug 2020 01:24:19
User entered '14 Aug 2020 21:24'	System	15 Aug 2020 01:24:19

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 17:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 2'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:42', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '161d5a72-59fd-41f1-b41b-24e7e58077d9'	System	16 Aug 2020 01:16:27
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 01:16:27

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:15:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '161d5a72-59fd-41f1-b41b-24e7e58077d9'	System	16 Aug 2020 01:16:27
User entered 'No (N)'	System	16 Aug 2020 01:16:27

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '161d5a72-59fd-41f1-b41b-24e7e58077d9'	System	16 Aug 2020 01:16:27
User entered 'No (N)'	System	16 Aug 2020 01:16:27

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:09', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '161d5a72-59fd-41f1-b41b-24e7e58077d9'	System	16 Aug 2020 01:16:27
User entered 'None (1)'	System	16 Aug 2020 01:16:27

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:24', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '161d5a72-59fd-41f1-b41b-24e7e58077d9'	System	16 Aug 2020 01:16:27
User entered '15 Aug 2020 21:16'	System	16 Aug 2020 01:16:27

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 3'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '9f23bc41-dbaf-4850-a92a-12a6fc2e1a03'	System	17 Aug 2020 00:55:04
User entered 'None (1)'	System	17 Aug 2020 00:55:04

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:36', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '9f23bc41-dbaf-4850-a92a-12a6fc2e1a03'	System	17 Aug 2020 00:55:04
User entered 'No (N)'	System	17 Aug 2020 00:55:04

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:39', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '9f23bc41-dbaf-4850-a92a-12a6fc2e1a03'	System	17 Aug 2020 00:55:04
User entered 'No (N)'	System	17 Aug 2020 00:55:04

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '9f23bc41-dbaf-4850-a92a-12a6fc2e1a03'	System	17 Aug 2020 00:55:04
User entered 'None (1)'	System	17 Aug 2020 00:55:04

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:54:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '9f23bc41-dbaf-4850-a92a-12a6fc2e1a03'	System	17 Aug 2020 00:55:04
User entered '16 Aug 2020 20:54'	System	17 Aug 2020 00:55:04

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 4'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7784a5bc-a0e9-4fe5-9892-351c65277a98'	System	18 Aug 2020 00:39:42
User entered 'None (1)'	System	18 Aug 2020 00:39:42

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7784a5bc-a0e9-4fe5-9892-351c65277a98'	System	18 Aug 2020 00:39:42
User entered 'No (N)'	System	18 Aug 2020 00:39:42

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7784a5bc-a0e9-4fe5-9892-351c65277a98'	System	18 Aug 2020 00:39:42
User entered 'No (N)'	System	18 Aug 2020 00:39:42

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:29', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7784a5bc-a0e9-4fe5-9892-351c65277a98'	System	18 Aug 2020 00:39:42
User entered 'None (1)'	System	18 Aug 2020 00:39:42

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7784a5bc-a0e9-4fe5-9892-351c65277a98'	System	18 Aug 2020 00:39:42
User entered '17 Aug 2020 20:39'	System	18 Aug 2020 00:39:42

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 5'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:39', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02a8e455-d46f-416e-b689-75be23445ce0'	System	19 Aug 2020 05:04:57
User entered 'None (1)'	System	19 Aug 2020 05:04:57

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:44', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02a8e455-d46f-416e-b689-75be23445ce0'	System	19 Aug 2020 05:04:57
User entered 'No (N)'	System	19 Aug 2020 05:04:57

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:47', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02a8e455-d46f-416e-b689-75be23445ce0'	System	19 Aug 2020 05:04:57
User entered 'No (N)'	System	19 Aug 2020 05:04:57

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:50', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02a8e455-d46f-416e-b689-75be23445ce0'	System	19 Aug 2020 05:04:57
User entered 'None (1)'	System	19 Aug 2020 05:04:57

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:04:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02a8e455-d46f-416e-b689-75be23445ce0'	System	19 Aug 2020 05:04:57
User entered '19 Aug 2020 01:04'	System	19 Aug 2020 05:04:57

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 6'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f391e67-986a-400f-bd8e-cf0298755539'	System	20 Aug 2020 00:40:55
User entered 'None (1)'	System	20 Aug 2020 00:40:55

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f391e67-986a-400f-bd8e-cf0298755539'	System	20 Aug 2020 00:40:55
User entered 'No (N)'	System	20 Aug 2020 00:40:55

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:42', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f391e67-986a-400f-bd8e-cf0298755539'	System	20 Aug 2020 00:40:55
User entered 'No (N)'	System	20 Aug 2020 00:40:55

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:45', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f391e67-986a-400f-bd8e-cf0298755539'	System	20 Aug 2020 00:40:55
User entered 'None (1)'	System	20 Aug 2020 00:40:55

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f391e67-986a-400f-bd8e-cf0298755539'	System	20 Aug 2020 00:40:55
User entered '19 Aug 2020 20:40'	System	20 Aug 2020 00:40:55

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 7'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:17:57', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dc4a8fe-9ad7-4ef0-87c3-ba49f9b2905c'	System	21 Aug 2020 02:19:17
User entered 'None (1)'	System	21 Aug 2020 02:19:17

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:18:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dc4a8fe-9ad7-4ef0-87c3-ba49f9b2905c'	System	21 Aug 2020 02:19:17
User entered 'No (N)'	System	21 Aug 2020 02:19:17

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:18:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dc4a8fe-9ad7-4ef0-87c3-ba49f9b2905c'	System	21 Aug 2020 02:19:17
User entered 'No (N)'	System	21 Aug 2020 02:19:17

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:18:12', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dc4a8fe-9ad7-4ef0-87c3-ba49f9b2905c'	System	21 Aug 2020 02:19:17
User entered 'None (1)'	System	21 Aug 2020 02:19:17

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:13', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dc4a8fe-9ad7-4ef0-87c3-ba49f9b2905c'	System	21 Aug 2020 02:19:17
User entered '20 Aug 2020 22:19'	System	21 Aug 2020 02:19:17

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:37', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:40', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:42', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'None (0)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered 'No (N)'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T13:57:57', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '78c0d81a-9b69-4f32-9598-7f16cb4e1b72'	System	14 Aug 2020 17:58:03
User entered '14 Aug 2020 13:57'	System	14 Aug 2020 17:58:03

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 13:35'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 16:05'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:40', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'None (0)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:45', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'None (0)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:49', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'None (0)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'None (0)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:24:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'None (0)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:25:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered 'No (N)'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-14T21:25:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '97240d54-f1de-4fcd-9209-e90bf37890a7'	System	15 Aug 2020 01:25:19
User entered '14 Aug 2020 21:25'	System	15 Aug 2020 01:25:19

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Aug 2020 17:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 2'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:51', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:16:59', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:17:02', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:17:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:17:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'None (0)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:17:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered 'No (N)'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-15T21:17:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '015e9480-d317-4bb7-942f-e846df44dca5'	System	16 Aug 2020 01:17:25
User entered '15 Aug 2020 21:17'	System	16 Aug 2020 01:17:25

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 3'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:17', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:20', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'None (0)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:24', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered 'No (N)'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-16T20:55:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1e770e5c-34a6-46e6-870a-25383010266b'	System	17 Aug 2020 00:55:35
User entered '16 Aug 2020 20:55'	System	17 Aug 2020 00:55:35

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 4'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:49', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:39:57', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'None (0)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:40:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered 'No (N)'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-17T20:40:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b7ffc43-938c-48f8-8076-3b0f1353b2cd'	System	18 Aug 2020 00:40:08
User entered '17 Aug 2020 20:40'	System	18 Aug 2020 00:40:08

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 5'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:09', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:12', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'None (0)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:18', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered 'No (N)'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T01:05:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1f48a6b2-31bb-4403-998d-89b04e9b0cdc'	System	19 Aug 2020 05:05:31
User entered '19 Aug 2020 01:05'	System	19 Aug 2020 05:05:31

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 6'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:40:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:04', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:07', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:10', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:12', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'None (0)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered 'No (N)'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-19T20:41:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'cdb1eebb-30c2-40fe-b383-4b2267c0ee8f'	System	20 Aug 2020 00:41:34
User entered '19 Aug 2020 20:41'	System	20 Aug 2020 00:41:34

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 7'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:19:59', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'None (0)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:20:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered 'No (N)'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-08-20T22:20:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '77cafa41-fd47-4365-95f2-eb28d0bdb593'	System	21 Aug 2020 02:20:10
User entered '20 Aug 2020 22:20'	System	21 Aug 2020 02:20:10

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:18:15

US3412246

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:15:06

US3412246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:15:06

US3412246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:15:06

US3412246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:15:06

US3412246

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:15:13

US3412246

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	21 Aug 2020 19:15:13

US3412246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:33:28

US3412246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:33:28

US3412246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:33:28

US3412246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:33:28

US3412246

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:33:36

US3412246

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	28 Aug 2020 19:33:36

US3412246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Sep 2020 13:31:36

US3412246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '4 Sep 2020'	Mason Urban (b) (4)	04 Sep 2020 13:31:36

US3412246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Sep 2020 13:31:36

US3412246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	Mason Urban (b) (4)	04 Sep 2020 13:31:36

US3412246

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Sep 2020 13:31:44

US3412246

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	04 Sep 2020 13:31:44

US3412246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:09:33

US3412246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:09:33

US3412246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:09:33

US3412246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'VISIT2'	System	11 Sep 2020 17:09:33

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:27'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '11 Sep 2020 12:27'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '36.6' C	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '76'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'bpm'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '16'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'breaths/min'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '110'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'mmHg'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '72'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'mmHg'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '13:46'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '11 Sep 2020 13:46'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
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)	29 Sep 2020 13:04:22
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 'temperature is within range. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 17:10:23
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	24 Sep 2020 17:10:05
User entered '96.7' F	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '68'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'bpm'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '16'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'breaths/min'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '110'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'mmHg'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '70'	Jacob sekinger (b) (4)	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'mmHg'	System	24 Sep 2020 17:10:05

US3412246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 17:11:34

US3412246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 17:11:34

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User closed query 'Per CDM: Please complete all the applicable pages in Visit 2' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:16:02
Query 'Per CDM: Please complete all the applicable pages in Visit 2' answered with 'updated' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 17:20:18
User opened query 'Per CDM: Please complete all the applicable pages in Visit 2' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 16:14:37
User entered 'Yes (Y)'		11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '13:10'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '11 Sep 2020 13:10'	System	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'ONCE'	System	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:12:22

US3412246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 17:11:55

US3412246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 17:11:55

US3412246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:40'	Jacob sekinger (b) (4)	24 Sep 2020 17:11:55

US3412246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '11 Sep 2020 12:40'	System	24 Sep 2020 17:11:55

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '12:34'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '11 Sep 2020 12:34'	System	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Jacob sekinger (b) (4)	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	24 Sep 2020 17:13:49

US3412246

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:49:24

US3412246

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '1'	System	18 Sep 2020 12:49:24

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:41:13', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02de9033-f3a8-4a59-a174-d2abc6ab0d95'	System	11 Sep 2020 17:41:40
User entered 'Yes (Y)'	System	11 Sep 2020 17:41:40

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:41:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02de9033-f3a8-4a59-a174-d2abc6ab0d95'	System	11 Sep 2020 17:41:40
User entered '96.7'	System	11 Sep 2020 17:41:40

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:41:30', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02de9033-f3a8-4a59-a174-d2abc6ab0d95'	System	11 Sep 2020 17:41:40
User entered 'No (N)'	System	11 Sep 2020 17:41:40

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:41:36', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '02de9033-f3a8-4a59-a174-d2abc6ab0d95'	System	11 Sep 2020 17:41:40
User entered '11 Sep 2020 13:41'	System	11 Sep 2020 17:41:40

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 13:30'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:26:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	System	12 Sep 2020 02:28:02
User entered 'Yes (Y)'	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	System	12 Sep 2020 02:28:02
User entered '98.5'	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	System	12 Sep 2020 02:28:02
User entered 'Yes (Y)'	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 15:25:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:25:14
User entered '1'	System	12 Sep 2020 02:28:02
	System	12 Sep 2020 02:28:02
	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	System	12 Sep 2020 02:28:02
User entered '0'	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:26', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '14ea7fdb-01ce-4348-8d66-c955936551a3'	System	12 Sep 2020 02:28:02
User entered '11 Sep 2020 22:27'	System	12 Sep 2020 02:28:02

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:55'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 2'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:33', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	System	13 Sep 2020 01:52:00
User entered 'Yes (Y)'	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	System	13 Sep 2020 01:52:00
User entered '98.6'	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	System	13 Sep 2020 01:52:00
User entered 'Yes (Y)'	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 15:25:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	15 Oct 2020 20:25:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:49', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	(b) (4)	
User entered '1'	System	13 Sep 2020 01:52:00
	System	13 Sep 2020 01:52:00
	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:49', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	System	13 Sep 2020 01:52:00
User entered '0'	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:51:54', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '80d77823-51e2-49b8-a149-cdd6daa6f858'	System	13 Sep 2020 01:52:00
User entered '12 Sep 2020 21:51'	System	13 Sep 2020 01:52:00

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 3'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	System	14 Sep 2020 02:48:51
User entered 'Yes (Y)'	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	System	14 Sep 2020 02:48:51
User entered '98.4'	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:37', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	System	14 Sep 2020 02:48:51
User entered 'Yes (Y)'	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 15:25:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	15 Oct 2020 20:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:41', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	(b) (4)	
User entered '1'	System	14 Sep 2020 02:48:51
	System	14 Sep 2020 02:48:51
	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:41', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	System	14 Sep 2020 02:48:51
User entered '0'	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:48:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f174cfda-cfe6-4d65-8af5-c775f7413896'	System	14 Sep 2020 02:48:51
User entered '13 Sep 2020 22:48'	System	14 Sep 2020 02:48:51

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 4'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:22:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3594cc13-a0df-4b3c-807b-79ad040834dc'	System	15 Sep 2020 04:23:23
User entered 'Yes (Y)'	System	15 Sep 2020 04:23:23

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:07', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3594cc13-a0df-4b3c-807b-79ad040834dc'	System	15 Sep 2020 04:23:23
User entered '97.8'	System	15 Sep 2020 04:23:23

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3594cc13-a0df-4b3c-807b-79ad040834dc'	System	15 Sep 2020 04:23:23
User entered 'No (N)'	System	15 Sep 2020 04:23:23

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:20', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3594cc13-a0df-4b3c-807b-79ad040834dc'	System	15 Sep 2020 04:23:23
User entered '15 Sep 2020 00:23'	System	15 Sep 2020 04:23:23

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 5'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:04:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ea110924-ab09-4b80-afe8-289c3a56bf18'	System	16 Sep 2020 02:05:27
User entered 'Yes (Y)'	System	16 Sep 2020 02:05:27

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ea110924-ab09-4b80-afe8-289c3a56bf18'	System	16 Sep 2020 02:05:27
User entered '97.6'	System	16 Sep 2020 02:05:27

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ea110924-ab09-4b80-afe8-289c3a56bf18'	System	16 Sep 2020 02:05:27
User entered 'No (N)'	System	16 Sep 2020 02:05:27

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:24', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ea110924-ab09-4b80-afe8-289c3a56bf18'	System	16 Sep 2020 02:05:27
User entered '15 Sep 2020 22:05'	System	16 Sep 2020 02:05:27

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 6'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2b9f2585-8b49-49fd-a2fd-23bd284227c6'	System	17 Sep 2020 02:35:32
User entered 'Yes (Y)'	System	17 Sep 2020 02:35:32

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2b9f2585-8b49-49fd-a2fd-23bd284227c6'	System	17 Sep 2020 02:35:32
User entered '97.7'	System	17 Sep 2020 02:35:32

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2b9f2585-8b49-49fd-a2fd-23bd284227c6'	System	17 Sep 2020 02:35:32
User entered 'No (N)'	System	17 Sep 2020 02:35:32

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:27', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2b9f2585-8b49-49fd-a2fd-23bd284227c6'	System	17 Sep 2020 02:35:32
User entered '16 Sep 2020 22:35'	System	17 Sep 2020 02:35:32

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 7'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:13', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ed67721b-cda8-4b56-af8f-03a402dac3c3'	System	18 Sep 2020 02:32:30
User entered 'Yes (Y)'	System	18 Sep 2020 02:32:30

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:17', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ed67721b-cda8-4b56-af8f-03a402dac3c3'	System	18 Sep 2020 02:32:30
User entered '97.0'	System	18 Sep 2020 02:32:30

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:23', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ed67721b-cda8-4b56-af8f-03a402dac3c3'	System	18 Sep 2020 02:32:30
User entered 'No (N)'	System	18 Sep 2020 02:32:30

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:27', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ed67721b-cda8-4b56-af8f-03a402dac3c3'	System	18 Sep 2020 02:32:30
User entered '17 Sep 2020 22:32'	System	18 Sep 2020 02:32:30

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:42:54', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '88a84ff5-9e81-4328-a10f-1fc164619340'	System	11 Sep 2020 17:43:19
User entered 'None (1)'	System	11 Sep 2020 17:43:19

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:42:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '88a84ff5-9e81-4328-a10f-1fc164619340'	System	11 Sep 2020 17:43:19
User entered 'No (N)'	System	11 Sep 2020 17:43:19

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '88a84ff5-9e81-4328-a10f-1fc164619340'	System	11 Sep 2020 17:43:19
User entered 'No (N)'	System	11 Sep 2020 17:43:19

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '88a84ff5-9e81-4328-a10f-1fc164619340'	System	11 Sep 2020 17:43:19
User entered 'None (1)'	System	11 Sep 2020 17:43:19

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '88a84ff5-9e81-4328-a10f-1fc164619340'	System	11 Sep 2020 17:43:19
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 17:43:19

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 13:30'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:50', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fd2aedcd-62c7-4dcd-b4f1-5a0c4f1f7222'	System	12 Sep 2020 02:28:30
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 02:28:30

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:27:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fd2aedcd-62c7-4dcd-b4f1-5a0c4f1f7222'	System	12 Sep 2020 02:28:30
User entered 'No (N)'	System	12 Sep 2020 02:28:30

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fd2aedcd-62c7-4dcd-b4f1-5a0c4f1f7222'	System	12 Sep 2020 02:28:30
User entered 'No (N)'	System	12 Sep 2020 02:28:30

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:04', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fd2aedcd-62c7-4dcd-b4f1-5a0c4f1f7222'	System	12 Sep 2020 02:28:30
User entered 'None (1)'	System	12 Sep 2020 02:28:30

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:09', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fd2aedcd-62c7-4dcd-b4f1-5a0c4f1f7222'	System	12 Sep 2020 02:28:30
User entered '11 Sep 2020 22:28'	System	12 Sep 2020 02:28:30

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:55'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 2'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:04', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dafdf7f-0620-426c-b36d-539c553baa15'	System	13 Sep 2020 01:52:36
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 01:52:36

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dafdf7f-0620-426c-b36d-539c553baa15'	System	13 Sep 2020 01:52:36
User entered 'No (N)'	System	13 Sep 2020 01:52:36

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:12', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dafdf7f-0620-426c-b36d-539c553baa15'	System	13 Sep 2020 01:52:36
User entered 'No (N)'	System	13 Sep 2020 01:52:36

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dafdf7f-0620-426c-b36d-539c553baa15'	System	13 Sep 2020 01:52:36
User entered 'None (1)'	System	13 Sep 2020 01:52:36

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5dafdf7f-0620-426c-b36d-539c553baa15'	System	13 Sep 2020 01:52:36
User entered '12 Sep 2020 21:52'	System	13 Sep 2020 01:52:36

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 3'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:18', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a10ace03-9166-4664-bc7a-d1f58434458e'	System	14 Sep 2020 02:49:47
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 02:49:47

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a10ace03-9166-4664-bc7a-d1f58434458e'	System	14 Sep 2020 02:49:47
User entered 'No (N)'	System	14 Sep 2020 02:49:47

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:26', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a10ace03-9166-4664-bc7a-d1f58434458e'	System	14 Sep 2020 02:49:47
User entered 'No (N)'	System	14 Sep 2020 02:49:47

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:29', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a10ace03-9166-4664-bc7a-d1f58434458e'	System	14 Sep 2020 02:49:47
User entered 'None (1)'	System	14 Sep 2020 02:49:47

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a10ace03-9166-4664-bc7a-d1f58434458e'	System	14 Sep 2020 02:49:47
User entered '13 Sep 2020 22:49'	System	14 Sep 2020 02:49:47

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 4'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2915fe02-4b22-4fe5-8c57-9087695b7699'	System	15 Sep 2020 04:23:51
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 04:23:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2915fe02-4b22-4fe5-8c57-9087695b7699'	System	15 Sep 2020 04:23:51
User entered 'No (N)'	System	15 Sep 2020 04:23:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:37', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2915fe02-4b22-4fe5-8c57-9087695b7699'	System	15 Sep 2020 04:23:51
User entered 'No (N)'	System	15 Sep 2020 04:23:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:40', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2915fe02-4b22-4fe5-8c57-9087695b7699'	System	15 Sep 2020 04:23:51
User entered 'None (1)'	System	15 Sep 2020 04:23:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:47', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2915fe02-4b22-4fe5-8c57-9087695b7699'	System	15 Sep 2020 04:23:51
User entered '15 Sep 2020 00:23'	System	15 Sep 2020 04:23:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 5'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'd24ef97a-5536-4b5e-a727-4b8208ad8d85'	System	16 Sep 2020 02:05:54
User entered 'None (1)'	System	16 Sep 2020 02:05:54

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:39', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'd24ef97a-5536-4b5e-a727-4b8208ad8d85'	System	16 Sep 2020 02:05:54
User entered 'No (N)'	System	16 Sep 2020 02:05:54

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:42', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'd24ef97a-5536-4b5e-a727-4b8208ad8d85'	System	16 Sep 2020 02:05:54
User entered 'No (N)'	System	16 Sep 2020 02:05:54

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:45', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'd24ef97a-5536-4b5e-a727-4b8208ad8d85'	System	16 Sep 2020 02:05:54
User entered 'None (1)'	System	16 Sep 2020 02:05:54

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:51', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'd24ef97a-5536-4b5e-a727-4b8208ad8d85'	System	16 Sep 2020 02:05:54
User entered '15 Sep 2020 22:05'	System	16 Sep 2020 02:05:54

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 6'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ee49b271-c2bb-41da-9e9c-909e25716367'	System	17 Sep 2020 02:35:55
User entered 'None (1)'	System	17 Sep 2020 02:35:55

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ee49b271-c2bb-41da-9e9c-909e25716367'	System	17 Sep 2020 02:35:55
User entered 'No (N)'	System	17 Sep 2020 02:35:55

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:39', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ee49b271-c2bb-41da-9e9c-909e25716367'	System	17 Sep 2020 02:35:55
User entered 'No (N)'	System	17 Sep 2020 02:35:55

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ee49b271-c2bb-41da-9e9c-909e25716367'	System	17 Sep 2020 02:35:55
User entered 'None (1)'	System	17 Sep 2020 02:35:55

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:50', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'ee49b271-c2bb-41da-9e9c-909e25716367'	System	17 Sep 2020 02:35:55
User entered '16 Sep 2020 22:35'	System	17 Sep 2020 02:35:55

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 7'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a72868bd-0079-4ef9-a440-4f89d1b0e84b'	System	18 Sep 2020 02:32:51
User entered 'None (1)'	System	18 Sep 2020 02:32:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a72868bd-0079-4ef9-a440-4f89d1b0e84b'	System	18 Sep 2020 02:32:51
User entered 'No (N)'	System	18 Sep 2020 02:32:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a72868bd-0079-4ef9-a440-4f89d1b0e84b'	System	18 Sep 2020 02:32:51
User entered 'No (N)'	System	18 Sep 2020 02:32:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:41', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a72868bd-0079-4ef9-a440-4f89d1b0e84b'	System	18 Sep 2020 02:32:51
User entered 'None (1)'	System	18 Sep 2020 02:32:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:47', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a72868bd-0079-4ef9-a440-4f89d1b0e84b'	System	18 Sep 2020 02:32:51
User entered '17 Sep 2020 22:32'	System	18 Sep 2020 02:32:51

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:19', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:21', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:28', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:30', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:34', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'None (0)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered 'No (N)'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T13:43:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '492a4986-eedf-4000-a9b4-73e196f032ee'	System	11 Sep 2020 17:43:52
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 17:43:52

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 13:30'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:16', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'No interference with activity (1)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:30', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'No interference with activity (1)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'None (0)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:40', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'None (0)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'None (0)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'None (0)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:28:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered 'No (N)'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-11T22:29:02', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '6394fa99-e0d3-4d89-b05a-2b4b13da4d40'	System	12 Sep 2020 02:29:08
User entered '11 Sep 2020 22:29'	System	12 Sep 2020 02:29:08

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '11 Sep 2020 16:55'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 2'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:37', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:44', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'None (0)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:48', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'None (0)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'None (0)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'None (0)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:52:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'None (0)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:53:02', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered 'No (N)'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-12T21:53:14', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '75948138-7fba-49c9-a607-b2185b8ddf1a'	System	13 Sep 2020 01:53:15
User entered '12 Sep 2020 21:53'	System	13 Sep 2020 01:53:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 3'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:49:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:50:02', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:50:05', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:50:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'None (0)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:50:12', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered 'No (N)'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-13T22:50:20', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '50e9be81-798c-4cbc-bb49-c5d75b6a6d03'	System	14 Sep 2020 02:50:23
User entered '13 Sep 2020 22:50'	System	14 Sep 2020 02:50:23

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 4'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:52', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:23:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:24:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:24:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:24:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'None (0)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:24:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered 'No (N)'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T00:24:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '67a7e7ad-37d7-4bda-a2e8-97374af4491d'	System	15 Sep 2020 04:24:19
User entered '15 Sep 2020 00:24'	System	15 Sep 2020 04:24:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 5'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:05:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'None (0)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered 'No (N)'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-15T22:06:16', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '31cfcdba-6aec-4d30-af0f-733acf045664'	System	16 Sep 2020 02:06:19
User entered '15 Sep 2020 22:06'	System	16 Sep 2020 02:06:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 6'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:35:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:08', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'None (0)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered 'No (N)'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-16T22:36:15', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '22cf8a8a-0ee9-44d1-8c00-fbc560d50907'	System	17 Sep 2020 02:36:19
User entered '16 Sep 2020 22:36'	System	17 Sep 2020 02:36:19

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	11 Sep 2020 17:12:22
User entered 'Day 7'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:51', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:55', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:32:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:33:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:33:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'None (0)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

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)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:33:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered 'No (N)'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-09-17T22:33:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ff49fa8-2aea-41d7-b58c-116cb5930632'	System	18 Sep 2020 02:33:15
User entered '17 Sep 2020 22:33'	System	18 Sep 2020 02:33:15

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:12:22

US3412246

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:12:22

US3412246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:53:02

US3412246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:53:02

US3412246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:53:02

US3412246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:53:02

US3412246

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:53:07

US3412246

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	18 Sep 2020 12:53:07

US3412246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 15:48:06

US3412246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '25 Sep 2020'	Mason Urban (b) (4)	25 Sep 2020 15:48:06

US3412246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Sep 2020 15:48:06

US3412246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	Mason Urban (b) (4)	25 Sep 2020 15:48:06

US3412246

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 15:48:13

US3412246

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	25 Sep 2020 15:48:13

US3412246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Oct 2020 17:02:08

US3412246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered '2 Oct 2020'	Mason Urban (b) (4)	02 Oct 2020 17:02:08

US3412246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	02 Oct 2020 17:02:08

US3412246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered empty.	Mason Urban (b) (4)	02 Oct 2020 17:02:08

US3412246

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Oct 2020 17:02:12

US3412246

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	02 Oct 2020 17:02:12

US3412246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 17:48:13

US3412246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:48:13

US3412246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	09 Oct 2020 17:48:13

US3412246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'VISIT3'	System	09 Oct 2020 17:48:13

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered empty.	System	09 Oct 2020 17:48:25

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24

US3412246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24

US3412246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Nov 2020 17:13:14
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:02

US3412246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	03 Nov 2020 17:13:14
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:02

US3412246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:48

US3412246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:48

US3412246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered '11:40'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:48

US3412246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered '9 Oct 2020 11:40'	System	09 Oct 2020 17:49:48

US3412246

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:32
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 17:49:55

US3412246

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:24
User entered 'I'	System	09 Oct 2020 17:49:55

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 64'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 71'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-22T21:27:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7f2da627-85f2-4dbe-8783-1fe20275302e'	System	23 Oct 2020 01:27:55
User entered 'No (N)'	System	23 Oct 2020 01:27:55

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-22T21:27:36', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7f2da627-85f2-4dbe-8783-1fe20275302e'	System	23 Oct 2020 01:27:55
User entered 'No (N)'	System	23 Oct 2020 01:27:55

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-22T21:27:51', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7f2da627-85f2-4dbe-8783-1fe20275302e'	System	23 Oct 2020 01:27:55
User entered '22 Oct 2020 21:27:51'	System	23 Oct 2020 01:27:55

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 78'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-31T08:08:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'babea668-c8b4-4b6a-8b02-c4ca2ffd009d'	System	31 Oct 2020 12:08:56
User entered 'No (N)'	System	31 Oct 2020 12:08:56

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-31T08:08:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'babea668-c8b4-4b6a-8b02-c4ca2ffd009d'	System	31 Oct 2020 12:08:56
User entered 'No (N)'	System	31 Oct 2020 12:08:56

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-10-31T08:08:51', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'babea668-c8b4-4b6a-8b02-c4ca2ffd009d'	System	31 Oct 2020 12:08:56
User entered '31 Oct 2020 08:08:51'	System	31 Oct 2020 12:08:56

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 92'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-11-14T00:40:45', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2749d6a5-090c-4e8c-836d-46cb28e96bf9'	System	14 Nov 2020 05:41:06
User entered 'No (N)'	System	14 Nov 2020 05:41:06

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-11-14T00:40:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2749d6a5-090c-4e8c-836d-46cb28e96bf9'	System	14 Nov 2020 05:41:06
User entered 'No (N)'	System	14 Nov 2020 05:41:06

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-11-14T00:41:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2749d6a5-090c-4e8c-836d-46cb28e96bf9'	System	14 Nov 2020 05:41:06
User entered '14 Nov 2020 00:41:01'	System	14 Nov 2020 05:41:06

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:34
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered 'Day 99'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:18:15

US3412246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:54
Data entry locked.	System	14 Aug 2020 17:18:15
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:18:15

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-11-25T00:31:59', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '85e02551-c878-4325-930e-9c5a05147ce7'	System	25 Nov 2020 05:32:37
User entered 'No (N)'	System	25 Nov 2020 05:32:37

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-11-25T00:32:22', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '85e02551-c878-4325-930e-9c5a05147ce7'	System	25 Nov 2020 05:32:37
User entered 'No (N)'	System	25 Nov 2020 05:32:37

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-11-25T00:32:33', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '85e02551-c878-4325-930e-9c5a05147ce7'	System	25 Nov 2020 05:32:37
User entered '25 Nov 2020 00:32:33'	System	25 Nov 2020 05:32:37

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-11-29T00:47:16', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b4f230fa-bfcd-4808-8034-d01d40ecf1f7'	System	29 Nov 2020 05:47:29
User entered 'No (N)'	System	29 Nov 2020 05:47:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-11-29T00:47:21', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b4f230fa-bfcd-4808-8034-d01d40ecf1f7'	System	29 Nov 2020 05:47:29
User entered 'No (N)'	System	29 Nov 2020 05:47:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-11-29T00:47:27', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b4f230fa-bfcd-4808-8034-d01d40ecf1f7'	System	29 Nov 2020 05:47:29
User entered '29 Nov 2020 00:47:27'	System	29 Nov 2020 05:47:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-12-06T01:35:18', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f2ca602d-5903-4c5a-a2fd-832b99f62acd'	System	06 Dec 2020 06:35:33
User entered 'No (N)'	System	06 Dec 2020 06:35:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-12-06T01:35:25', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f2ca602d-5903-4c5a-a2fd-832b99f62acd'	System	06 Dec 2020 06:35:33
User entered 'No (N)'	System	06 Dec 2020 06:35:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-12-06T01:35:32', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f2ca602d-5903-4c5a-a2fd-832b99f62acd'	System	06 Dec 2020 06:35:33
User entered '06 Dec 2020 01:35:32'	System	06 Dec 2020 06:35:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-12-14T21:42:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0211f315-a577-4d20-8dea-15a4893681f5'	System	15 Dec 2020 02:42:52
User entered 'No (N)'	System	15 Dec 2020 02:42:52

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-12-14T21:42:40', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0211f315-a577-4d20-8dea-15a4893681f5'	System	15 Dec 2020 02:42:52
User entered 'No (N)'	System	15 Dec 2020 02:42:52

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-12-14T21:42:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0211f315-a577-4d20-8dea-15a4893681f5' User entered '14 Dec 2020 21:42:46'	System	15 Dec 2020 02:42:52

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-12-21T12:04:56', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a7789086-eb71-4b34-bf39-3153e2cf1007'	System	21 Dec 2020 17:05:13
User entered 'No (N)'	System	21 Dec 2020 17:05:13

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-12-21T12:05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a7789086-eb71-4b34-bf39-3153e2cf1007'	System	21 Dec 2020 17:05:13
User entered 'No (N)'	System	21 Dec 2020 17:05:13

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-12-21T12:05:11', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'a7789086-eb71-4b34-bf39-3153e2cf1007'	System	21 Dec 2020 17:05:13
User entered '21 Dec 2020 12:05:11'	System	21 Dec 2020 17:05:13

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2020-12-28T11:22:20', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fcb9ade6-ed7d-463b-8251-40dd690e1d35'	System	28 Dec 2020 16:22:35
User entered 'No (N)'	System	28 Dec 2020 16:22:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2020-12-28T11:22:24', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fcb9ade6-ed7d-463b-8251-40dd690e1d35'	System	28 Dec 2020 16:22:35
User entered 'No (N)'	System	28 Dec 2020 16:22:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2020-12-28T11:22:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'fcb9ade6-ed7d-463b-8251-40dd690e1d35'	System	28 Dec 2020 16:22:35
User entered '28 Dec 2020 11:22:31'	System	28 Dec 2020 16:22:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-01-03T09:43:26', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '06256155-06b0-43c2-a13b-c53a4181ea3b'	System	03 Jan 2021 14:43:46
User entered 'No (N)'	System	03 Jan 2021 14:43:46

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-01-03T09:43:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '06256155-06b0-43c2-a13b-c53a4181ea3b'	System	03 Jan 2021 14:43:46
User entered 'No (N)'	System	03 Jan 2021 14:43:46

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-01-03T09:43:41', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '06256155-06b0-43c2-a13b-c53a4181ea3b'	System	03 Jan 2021 14:43:46
User entered '03 Jan 2021 09:43:41'	System	03 Jan 2021 14:43:46

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-01-11T13:17:03', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '33ad30ec-680e-4a85-b9d5-c39fca8d07c5'	System	11 Jan 2021 18:17:16
User entered 'No (N)'	System	11 Jan 2021 18:17:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-01-11T13:17:06', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '33ad30ec-680e-4a85-b9d5-c39fca8d07c5'	System	11 Jan 2021 18:17:16
User entered 'No (N)'	System	11 Jan 2021 18:17:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-01-11T13:17:10', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '33ad30ec-680e-4a85-b9d5-c39fca8d07c5'	System	11 Jan 2021 18:17:16
User entered '11 Jan 2021 13:17:10'	System	11 Jan 2021 18:17:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-01-17T14:38:48', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'e562a153-4676-45c7-9ce8-249af53af7e8'	System	17 Jan 2021 19:39:07
User entered 'No (N)'	System	17 Jan 2021 19:39:07

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-01-17T14:39:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'e562a153-4676-45c7-9ce8-249af53af7e8'	System	17 Jan 2021 19:39:07
User entered 'No (N)'	System	17 Jan 2021 19:39:07

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-01-17T14:39:04', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'e562a153-4676-45c7-9ce8-249af53af7e8' User entered '17 Jan 2021 14:39:04'	System	17 Jan 2021 19:39:07
	System	17 Jan 2021 19:39:07

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-01-25T06:48:16', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7fe828d2-8041-42eb-b8b5-f3699b24c19d'	System	25 Jan 2021 11:48:35
User entered 'No (N)'	System	25 Jan 2021 11:48:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-01-25T06:48:20', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7fe828d2-8041-42eb-b8b5-f3699b24c19d'	System	25 Jan 2021 11:48:35
User entered 'No (N)'	System	25 Jan 2021 11:48:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-01-25T06:48:31', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '7fe828d2-8041-42eb-b8b5-f3699b24c19d'	System	25 Jan 2021 11:48:35
User entered '25 Jan 2021 06:48:31'	System	25 Jan 2021 11:48:35

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-02-04T14:26:38', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5303a4c3-3bf5-47b4-aacf-40d76088e005'	System	04 Feb 2021 14:30:12
User entered 'No (N)'	System	04 Feb 2021 14:30:12

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-02-04T14:26:43', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5303a4c3-3bf5-47b4-aacf-40d76088e005'	System	04 Feb 2021 14:30:12
User entered 'No (N)'	System	04 Feb 2021 14:30:12

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-04T14:26:47', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '5303a4c3-3bf5-47b4-aacf-40d76088e005' User entered '04 Feb 2021 14:26:47'	System	04 Feb 2021 14:30:12

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-02-08T15:59:26', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2cecd715-23f5-4c94-9c4c-7df220a74b19'	System	08 Feb 2021 20:59:39
User entered 'No (N)'	System	08 Feb 2021 20:59:39

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-02-08T15:59:30', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2cecd715-23f5-4c94-9c4c-7df220a74b19'	System	08 Feb 2021 20:59:39
User entered 'No (N)'	System	08 Feb 2021 20:59:39

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-08T15:59:33', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2cecd715-23f5-4c94-9c4c-7df220a74b19'	System	08 Feb 2021 20:59:39
User entered '08 Feb 2021 15:59:33'	System	08 Feb 2021 20:59:39

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-02-15T07:59:35', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '47ef5ecf-3ef2-4d2b-9583-bd154de923fc'	System	15 Feb 2021 12:59:51
User entered 'No (N)'	System	15 Feb 2021 12:59:51

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-02-15T07:59:41', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '47ef5ecf-3ef2-4d2b-9583-bd154de923fc'	System	15 Feb 2021 12:59:51
User entered 'No (N)'	System	15 Feb 2021 12:59:51

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-15T07:59:46', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '47ef5ecf-3ef2-4d2b-9583-bd154de923fc' User entered '15 Feb 2021 07:59:46'	System	15 Feb 2021 12:59:51
	System	15 Feb 2021 12:59:51

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-02-21T14:00:53', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f144acf8-e1aa-46be-96cc-1e4f723dbc8a'	System	21 Feb 2021 19:01:16
User entered 'No (N)'	System	21 Feb 2021 19:01:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-02-21T14:00:58', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f144acf8-e1aa-46be-96cc-1e4f723dbc8a'	System	21 Feb 2021 19:01:16
User entered 'No (N)'	System	21 Feb 2021 19:01:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-21T14:01:01', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'f144acf8-e1aa-46be-96cc-1e4f723dbc8a'	System	21 Feb 2021 19:01:16
User entered '21 Feb 2021 14:01:01'	System	21 Feb 2021 19:01:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-02-28T11:19:03-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b5ca604d-4a06-4242-97b0-7d12ebf65289'	System	28 Feb 2021 16:19:16
User entered 'No (N)'	System	28 Feb 2021 16:19:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-02-28T11:19:08-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b5ca604d-4a06-4242-97b0-7d12ebf65289'	System	28 Feb 2021 16:19:16
User entered 'No (N)'	System	28 Feb 2021 16:19:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-28T11:19:13-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: 'b5ca604d-4a06-4242-97b0-7d12ebf65289'	System	28 Feb 2021 16:19:16
User entered '28 Feb 2021 11:19:13'	System	28 Feb 2021 16:19:16

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-03-08T06:54:29-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered 'Yes (Y)'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-03-08T06:54:34-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered 'No (N)'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-03-08T06:54:42-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered 'No (N)'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-03-08T06:54:48-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered 'Yes (Y)'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Please 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 (c82a5698b4ffe4fd)', Time: '2021-03-08T06:55:03-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-03-08T06:55:18-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2ee25976-3815-445a-8de2-7a3a7f372f01'	System	08 Mar 2021 11:55:29
User entered '08 Mar 2021 06:55:18'	System	08 Mar 2021 11:55:29

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-03-18T14:21:16-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b052549-7dec-4ca0-8f93-9d476b88dc56'	System	18 Mar 2021 18:21:33
User entered 'No (N)'	System	18 Mar 2021 18:21:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-03-18T14:21:09-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b052549-7dec-4ca0-8f93-9d476b88dc56'	System	18 Mar 2021 18:21:33
User entered 'No (N)'	System	18 Mar 2021 18:21:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-03-18T14:21:27-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '1b052549-7dec-4ca0-8f93-9d476b88dc56'	System	18 Mar 2021 18:21:33
User entered '18 Mar 2021 14:21:27'	System	18 Mar 2021 18:21:33

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-03-29T07:34:11-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f043eac-bdeb-4f50-b7de-54256b8f1a2f' User entered 'No (N)'	System	29 Mar 2021 11:34:25
	System	29 Mar 2021 11:34:25

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-03-29T07:34:16-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f043eac-bdeb-4f50-b7de-54256b8f1a2f'	System	29 Mar 2021 11:34:25
User entered 'No (N)'	System	29 Mar 2021 11:34:25

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-03-29T07:34:20-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '3f043eac-bdeb-4f50-b7de-54256b8f1a2f' User entered '29 Mar 2021 07:34:20'	System	29 Mar 2021 11:34:25
	System	29 Mar 2021 11:34:25

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-04-06T13:25:40-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '4d3fe4cd-cc8c-4ca9-96bc-d270316c760b'	System	06 Apr 2021 17:25:57
User entered 'No (N)'	System	06 Apr 2021 17:25:57

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-04-06T13:25:45-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '4d3fe4cd-cc8c-4ca9-96bc-d270316c760b'	System	06 Apr 2021 17:25:57
User entered 'No (N)'	System	06 Apr 2021 17:25:57

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-04-06T13:25:50-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '4d3fe4cd-cc8c-4ca9-96bc-d270316c760b'	System	06 Apr 2021 17:25:57
User entered '06 Apr 2021 13:25:50'	System	06 Apr 2021 17:25:57

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-04-20T20:16:42-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '10c27564-621f-4452-9923-8dcf751a03f7'	System	21 Apr 2021 00:16:55
User entered 'No (N)'	System	21 Apr 2021 00:16:55

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-04-20T20:16:47-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '10c27564-621f-4452-9923-8dcf751a03f7'	System	21 Apr 2021 00:16:55
User entered 'No (N)'	System	21 Apr 2021 00:16:55

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-04-20T20:16:51-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '10c27564-621f-4452-9923-8dcf751a03f7'	System	21 Apr 2021 00:16:55
User entered '20 Apr 2021 20:16:51'	System	21 Apr 2021 00:16:55

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-04-29T14:54:35-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0b27fe6e-6525-431e-b061-e7d5a2fc3abc'	System	29 Apr 2021 18:54:48
User entered 'No (N)'	System	29 Apr 2021 18:54:48

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-04-29T14:54:39-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0b27fe6e-6525-431e-b061-e7d5a2fc3abc'	System	29 Apr 2021 18:54:48
User entered 'No (N)'	System	29 Apr 2021 18:54:48

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-04-29T14:54:42-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '0b27fe6e-6525-431e-b061-e7d5a2fc3abc'	System	29 Apr 2021 18:54:48
User entered '29 Apr 2021 14:54:42'	System	29 Apr 2021 18:54:48

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:15-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered 'Yes (Y)'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

Have you been exposed to someone with 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 (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:19-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered 'No (N)'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:25-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered 'No (N)'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[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 (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:33-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered 'Yes (Y)'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Please 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 (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:45-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-05-02T21:06:49-04:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '2df8b663-a8cd-4103-ad4b-9973fcc079d1'	System	03 May 2021 01:12:04
User entered '02 May 2021 21:06:49'	System	03 May 2021 01:12:04

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:31:54

US3412246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:54
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:31:54

US3412246

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:58

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 08:31:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-28T11:19:28-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '44515124-097d-4202-ad2c-149003731ad7'	System	28 Feb 2021 16:19:39
User entered 'No (N)'	System	28 Feb 2021 16:19:39

US3412246

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:31:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c82a5698b4ffe4fd)', Time: '2021-02-28T11:19:33-05:00', User OID: 'PatientReportedOutcome (US3412246)', ODM File OID: '44515124-097d-4202-ad2c-149003731ad7'	System	28 Feb 2021 16:19:39
User entered '28 Feb 2021 11:19:33'	System	28 Feb 2021 16:19:39

US3412246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Nov 2020 17:10:05

US3412246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:12
User entered '9 Nov 2020'	Mason Urban (b) (4)	09 Nov 2020 17:10:05

US3412246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Nov 2020 17:10:05

US3412246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:12
User entered empty.	Mason Urban (b) (4)	09 Nov 2020 17:10:05

US3412246

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Nov 2020 17:09:58

US3412246

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:17
User entered 'I'	System	09 Nov 2020 17:09:58

US3412246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Dec 2020 19:49:32

US3412246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '10 Dec 2020'	Mason Urban (b) (4)	10 Dec 2020 19:49:32

US3412246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Dec 2020 19:49:32

US3412246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	Mason Urban (b) (4)	10 Dec 2020 19:49:32

US3412246

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Dec 2020 19:49:46

US3412246

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User entered 'I'	System	10 Dec 2020 19:49:46

US3412246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 18:21:27

US3412246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '8 Jan 2021'	Mason Urban (b) (4)	08 Jan 2021 18:21:27

US3412246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Jan 2021 18:21:27

US3412246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	Mason Urban (b) (4)	08 Jan 2021 18:21:27

US3412246

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 18:21:36

US3412246

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User entered 'I'	System	08 Jan 2021 18:21:36

US3412246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Feb 2021 21:00:14

US3412246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '8 Feb 2021'	Mason Urban (b) (4)	08 Feb 2021 21:00:14

US3412246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Feb 2021 21:00:14

US3412246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	Mason Urban (b) (4)	08 Feb 2021 21:00:14

US3412246

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Feb 2021 21:00:26

US3412246

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:45
User entered 'I'	System	08 Feb 2021 21:00:26

US3412246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:52:22

US3412246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 13:52:22

US3412246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:52:22

US3412246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 13:52:22

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:58:58

US3412246

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:59:01

US3412246

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:59:01

US3412246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:59:06

US3412246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:59:06

US3412246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:59:06

US3412246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:59:06

US3412246

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:32:41

US3412246

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 18:32:41

US3412246

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:25:43

US3412246

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:25:43

US3412246

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	11 Jan 2021 20:25:43

US3412246

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 20:25:43

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User closed query 'Per CDM: Per sponsor review, Discontinued from Study is checked, however Study Discontinuation CRF is blank. Please review and update. ' (Site from DM).		19 Apr 2021 09:36:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Query 'Per CDM: Per sponsor review, Discontinued from Study is checked, however Study Discontinuation CRF is blank. Please review and update. ' answered with 'updated' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	08 Apr 2021 12:08:59
User opened query 'Per CDM: Per sponsor review, Discontinued from Study is checked, however Study Discontinuation CRF is blank. Please review and update. ' (Site from DM).	(b) (4)	08 Apr 2021 12:08:54
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 15:10:30
Amendment Manager inserted this DataPoint.	System	23 Mar 2021 17:48:19
		06 Mar 2021 12:40:00

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User closed query 'Per CDM: Subject Unblinded under Amendment 5 is checked. However, Amendment 6 or later is selected. Please review and reconcile. ' (Site from DM).		19 Apr 2021 09:36:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Query 'Per CDM: Subject Unblinded under Amendment 5 is checked. However, Amendment 6 or later is selected. Please review and reconcile. ' answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Subject Unblinded under Amendment 5 is checked. However, Amendment 6 or later is selected. Please review and reconcile. ' (Site from DM).	Andrea Newlands (b) (4)	08 Apr 2021 12:09:06
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	07 Apr 2021 15:11:12
Amendment Manager inserted this DataPoint.		23 Mar 2021 17:48:19
	System	06 Mar 2021 12:40:00

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:57:08
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:25:56
	(b) (4)	

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:57:08
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:25:56
	(b) (4)	

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'No (N)'	Mason Urban (b) (4)	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	11 Jan 2021 20:25:56

US3412246

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered empty.	System	11 Jan 2021 20:25:56

US3412246

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:26:11

US3412246

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:26:11

US3412246

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '13:37'	Mason Urban (b) (4)	11 Jan 2021 20:26:11

US3412246

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '11 Jan 2021 13:37'	System	11 Jan 2021 20:26:11

US3412246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:26:19

US3412246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:17
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:26:19

US3412246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:17
User entered '13:38'	Mason Urban (b) (4)	11 Jan 2021 20:26:19

US3412246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:47
User entered '11 Jan 2021 13:38'	System	11 Jan 2021 20:26:19

US3412246

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:44
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:37:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Mar 2021 16:21:56
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 17:14:06

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	25 Mar 2021 13:33:55
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:14:43
User entered	System	08 Mar 2021 17:14:39
'USA-US061-2021-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 17:14:39

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:33:57
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C6 - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 06:46:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 06:46:39
	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 19:50:35
Coding entries removed.	Steven Anderson (b) (4)	16 Mar 2021 19:49:46
	(b) (4)	
User entered 'Anterior osteophyte avulsion fracture C6' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Mar 2021 19:49:46
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Cervical spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 16:26:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 16:26:53
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 16:25:52
User entered 'Cervical Spondylosis'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:33:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:34:09
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:34:21
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:34:23
User entered '2 Mar 2021'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:34:25
User entered empty.	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	25 Mar 2021 13:34:28
	(b) (4), (b) (6)	24 Mar 2021 18:02:41
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).		24 Mar 2021 18:02:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		23 Mar 2021 17:53:30
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'end date unknown' (Site from Safety).		23 Mar 2021 17:52:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'end date id unknown' (Site from Safety).		15 Mar 2021 12:55:49
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).		15 Mar 2021 12:55:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:23:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:34:37
User entered empty.	Steven Anderson (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:34:39
User entered empty.	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:23:53
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		02 Apr 2021 16:19:06
User entered empty.	System	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:34:43
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:34:48
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:34:51
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:34:54
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:00:58
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'records have been faxed as of 1440 on 13APR2021' (Site from Safety).		13 Apr 2021 18:43:11
DataPoint Verified.		25 Mar 2021 13:34:58
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		17 Mar 2021 14:30:45
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	16 Mar 2021 20:53:57
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		16 Mar 2021 20:53:47
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		16 Mar 2021 20:53:47

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:56:14
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		15 Mar 2021 12:56:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 16:24:55
User entered 'I'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:20
User entered '2 Mar 2021'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:22
User entered '04 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Mar 2021 20:53:47
User entered empty.	(b) (4) Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:30
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	16 Mar 2021 20:53:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:53:03
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Mar 2021 16:24:55
User entered 'Unknown (UNK)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:32
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	23 Mar 2021 18:15:59
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		23 Mar 2021 18:15:59
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 18:15:59
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	16 Mar 2021 20:53:03
User entered empty.	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:36
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:38
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:40
User entered '0'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:42
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:44
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:46
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:51
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
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. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 16:48:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'information has been updated' (Site from DM). 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. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	Richard Powell (b) (4) (b) (4) (b) (4), (b) (6)	16 Apr 2021 13:32:01 14 Apr 2021 14:21:02 01 Apr 2021 11:55:17
User entered 'I'	(b) (4), (b) (6) Steven Anderson (b) (4)	25 Mar 2021 13:35:53 05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:35:56
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:15:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:01:17
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'information has been updated' (Site from Safety).		14 Apr 2021 14:23:03
DataPoint Un-verified.		14 Apr 2021 14:22:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error		14 Apr 2021 14:22:45
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		02 Apr 2021 16:19:37
DataPoint Verified.		25 Mar 2021 13:35:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:36:01
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please consider whether cervical spondylosis and spinal cord contusion as noted in the medical records meet AE/SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:26:07
Query 'IQVIA Medical query: Please consider whether cervical spondylosis and spinal cord contusion as noted in the medical records meet AE/SAE reporting criteria and update report if appropriate.' answered with 'information has been updated' (Site from Safety).		26 Apr 2021 12:19:42
User opened query 'IQVIA Medical query: Please consider whether cervical spondylosis and spinal cord contusion as noted in the medical records meet AE/SAE reporting criteria and update report if appropriate.' (Site from Safety).		23 Apr 2021 14:15:20
DataPoint Verified.		19 Apr 2021 16:07:42
User closed query 'please correct spelling of glaucoma' (Site from CRA).		19 Apr 2021 16:07:24
User closed query 'Per DM CLR: Narrative = WEAR ASPEN COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		16 Apr 2021 17:06:27
User closed query 'Per DM CLR: Narrative = TREATED WITH OXYCODONE, IV FENTANYL, IV HYDROMORPHINE, ACETAMINOPHEN, DOCUSATE-SENNA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		16 Apr 2021 17:05:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
Query 'Per DM CLR: Narrative = WEAR ASPEN COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:23:30

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = TREATED WITH OXYCODONE, IV FENTANYL, IV HYDROMORPHINE, ACETAMINOPHEN, DOCUSATE-SENNA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'list has been updated' (Site from DM). Query 'please correct spelling of glaucoma' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:23:24
		14 Apr 2021 14:23:10

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT WAS CALLED FOR A STUDY VISIT ON 05-MAR-2021 AND INDICATED HOSPITALIZATION FOR REAR END MVA COLLISION IN WHICH CERVICAL SPONDYLOSIS WAS SUSTAINED WITH RESULTANT NECK PAIN. SUBJECT PRESENT TO ED AS A 70 Y/O MALE WITH H/O OF glaucoma, INSOMNIA, AND HYPOGONADISM WITH ONSET OF UPPER EXTREMITY PAIN FOLLOWING A MVA ON 02MAR2021. RECEIVED BLINDED MRNA-1273 ON 14AUG2020 AND 11SEP2020. NONSMOKER. INITIAL PRESENTATION - STABLE VS, PE NORMAL WITH SUBJECT COMPLAINTS OF INCREASING UPPER EXTREMITY PAIN. SUBJECT WAS ADMITTED TO ICU FOR NEURO CHECK, LABS, AND STUDIES: CBC, CHEM PANEL, URINE, TOXICOLOGY SCREEN (NEGATIVE), COVID NP/OP SWAB RAPID SCREEN - NEGATIVE. IMAGING: CT HEAD, NECK, CHEST, ABDOMEN/PELVIS: CERVICAL SPONDYLOSIS C3/C4, MRI CERVICAL SPINE 02MAR2021 - ANTERIOR OSTEOPHYTE AVULSION FXR C6, MILD CORD EDEMA REPRESENTING SPINAL CORD CONTUSION, XRAY AP/LET CERVICAL SPINE - C6 OCCLUSION FXR. TREATED WITH OXYCODONE, IV FENTANYL, IV HYDROMORPHINE, ACETAMINOPHEN, DOCUSATE-SENNA. DISCHARGED ON 04 MAR2021 STABLE WITH INSTRUCTION TO WEAR ASPEN COLLAR, CONTINUED CURRENT MEDS AND ADDED ACETAMINOPHEN, GABAPENTINE, OXYCODONE, DOCUSATE-SENNA, AND FOLLOW-UP WITH NEUROSURGERY IN 1 WEEK.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:22:45
User opened query 'Per DM CLR: Narrative = WEAR ASPEN COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:55:10

PRODUCTION RELEASE (v12.003
EAB) (1725)

1671 of 2122

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = TREATED WITH OXYCODONE, IV FENTANYL, IV HYDROMORPHINE, ACETAMINOPHEN, DOCUSATE-SENNA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:54:56
User opened query 'please correct spelling of glaucoma' (Site from CRA).		25 Mar 2021 13:41:16
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).		17 Mar 2021 14:30:52
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:52:50

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT WAS CALLED FOR A STUDY VISIT ON 05-MAR-2021 AND INDICATED HOSPITALIZATION FOR REAR END MVA COLLISION IN WHICH CERVICAL SPONDYLOSIS WAS SUSTAINED WITH RESULTANT NECK PAIN. subject present to ED as a 70 y/o male with h/o of claugcomoa, insomnia, and hypogonadism with onset of upper extremity pain following a MVA on 02mar2021. received blinded mRNA-1273 on 14Aug2020 and 11Sep2020. Nonsmoker. Initial presentation - stable vs, PE normal with subject complaints of increasing upper extremity pain. subject was admitted to ICU for neuro check, labs, and studies: CBC, chem panel, urine, toxicology screen (negative), covid NP/OP swab rapid screen - negative. imaging: CT head, neck, chest, abdomen/pelvis: cervical spondylosis c3/c4, MRI cervical spine 02mar2021 - anterior osteophyte avulsion fxr c6, mild cord edema representing spinal cord contusion, xray AP/let cervical spine - c6 occlusion fxr. Treated with oxycodone, IV fentanyl, iv hydromorphone, acetaminophen, docusate-senna. discharged on 04 mar2021 stable with instruction to wear aspen collar, continued current meds and added acetaminophen, gabapentine, oxycodone, docusate-senna, and follow-up with neurosurgery in 1 week.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Mar 2021 20:52:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:56:28
User entered 'The subject was called for a study visit on 05-Mar-2021 and indicated hospitalization for rear end MVA collision in which cervical spondylosis was sustained with resultant neck pain.'	Steven Anderson (b) (4)	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 20:53:03
User entered '0'	System	05 Mar 2021 16:24:55

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Cervical spondylosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 08:37:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:37:40
Data point term sent to Coder	System	16 Mar 2021 20:52:48
User entered 'cervical spondylosis c4/c4'	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:00:49
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'confirmed' (Site from System).	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:52:20
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	16 Mar 2021 20:52:05
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'subject present to ED as a 70 y/o male with h/o of claugcomoa, insomnia, and hypogonadism with onset of upper extremity pain following a MVA on 02mar2021. received blinded mRNA-1273 on 14Aug2020 and 11Sep2020. Nonsmoker. Initial presentation - stable vs, PE normal with subject complaints of increasing upper extremity pain. subject was admitted to ICU for neuro check, labs, and studies: CBC, chem panel, urine, toxicology screen (negative), covid NP/OP swab rapid screen - negative. imaging: CT head, neck, chest, abdomen/pelvis: cervical spondylosis c3/c4, MRI cervical spine 02mar2021 - anterior osteophyte avulsion fxr c6, mild cord edema representing spinal cord contusion, xray AP/let cervical spine - c6 occlusion fxr. Treated with oxycodone, IV fentanyl, iv hydromorphone, acetaminophen, docusate-senna. discharged on 04 mar2021 stable with instruction to wear aspen collar, continued current meds and added acetaminophen, gabapentine, oxycodone, docusate-senna, and follow-up with neurosurgery in 1 week.'	Andrea Newlands (b) (4)	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 20:52:05

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Spinal cord injuries NEC, PT: Spinal cord injury, LLT: Spinal cord injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 11:57:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:57:43
Data point term sent to Coder	System	16 Mar 2021 20:55:53
User entered 'spinal cord contusion'	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:02:22
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'confirmed' (Site from System).	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:55:55
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	16 Mar 2021 20:55:49
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49
	(b) (4)	

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'subject present to ED as a 70 y/o male with h/o of claustraphobia, insomnia, and hypogonadism with onset of upper extremity pain following a MVA on 02mar2021. received blinded mRNA-1273 on 14Aug2020 and 11Sep2020. Nonsmoker. Initial presentation - stable vs, PE normal with subject complaints of increasing upper extremity pain. subject was admitted to ICU for neuro check, labs, and studies: CBC, chem panel, urine, toxicology screen (negative), covid NP/OP swab rapid screen - negative. imaging: CT head, neck, chest, abdomen/pelvis: cervical spondylosis c3/c4, MRI cervical spine 02mar2021 - anterior osteophyte avulsion fxr c6, mild cord edema representing spinal cord contusion, xray AP/let cervical spine - c6 occlusion fxr. Treated with oxycodone, IV fentanyl, iv hydromorphone, acetaminophen, docusate-senna. discharged on 04 mar2021 stable with instruction to wear aspen collar, continued current meds and added acetaminophen, gabapentine, oxycodone, docusate-senna, and follow-up with neurosurgery in 1 week.'	Andrea Newlands (b) (4)	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 20:55:49

US3412246

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 20:55:49

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:33:24

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 19:35:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 19:35:29
Data point term sent to Coder	System	20 Aug 2020 19:35:02
User entered 'AMBIEN'	(b) (4), (b) (6)	20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'INSOMNIA'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '10'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'mg (mg)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'once daily (QD)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Oral (ORAL)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:34:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:39:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:34:01
User entered 'UN UNK 2010'	(b) (4), (b) (6)	20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '0'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Yes (Y)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:24
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:34:01

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 19:35:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 19:35:29
Data point term sent to Coder	System	20 Aug 2020 19:35:03
User entered 'MULTIVITAMIN'	(b) (4), (b) (6)	20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:29
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Nov 2020 17:08:27
User entered 'No (N)'	(b) (4)	20 Aug 2020 19:34:30
	(b) (4), (b) (6)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:29
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'GENERAL HEALTH'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	5 Mar 2021 14:00:29
DataPoint Verified.	(b) (4), (b) (6)	5 Mar 2021 13:42:54
User entered 'I'		0 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'tablet (TABLET)'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'once daily (QD)'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Oral (ORAL)'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:34:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:39:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:34:30
User entered 'UN UNK 2000'	(b) (4), (b) (6)	20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '0'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Yes (Y)'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:29
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:29
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:34:30

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 09:34:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 09:34:12
Data point term sent to Coder	System	20 Aug 2020 19:38:08
User entered 'TESTOSTERONE'	(b) (4), (b) (6)	20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'HYPOGONADISM / LOW TESTOSTERONE'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '200'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'mg (mg)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'other (OTHER)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'BI-WEEKLY'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Intramuscular (INTRAMUSCULAR)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:34:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:38:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:37:19
User entered 'UN UNK 2003'	(b) (4), (b) (6)	20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '0'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Yes (Y)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:19
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:37:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:25:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:25:46
User closed query 'Per CDM re-query: Response indicates updated to 1 GTT; However no numerical recorded. Please review and update if appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:16:01
Data point term sent to Coder	System	19 Feb 2021 22:18:40
Query 'Per CDM re-query: Response indicates updated to 1 GTT; However no numerical recorded. Please review and update if appropriate else clarify. ' answered with "'gtt" referred to a drop, strength updated.' (Site from DM).	Andrea Newlands (b) (4)	19 Feb 2021 22:17:42
Coding entries removed.	Andrea Newlands (b) (4)	19 Feb 2021 22:17:39
User entered 'LUMIGAN (0.01%)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 22:17:39
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 18:36:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 18:36:20

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM). User opened query 'Per CDM re-query: Response indicates updated to 1 GTT; However no numerical recorded. Please review and update if appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:54:26
Data point term sent to Coder	System	27 Jan 2021 15:05:44
Query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' answered with 'UPDATED TO 1 GTTS PER SOURCE' (Site from DM).	Melissa Fuson (b) (4)	27 Jan 2021 15:05:37
Coding entries removed.	(b) (4)	
	Melissa Fuson (b) (4)	27 Jan 2021 15:05:17
User entered 'LUMIGAN (GTTS)' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	27 Jan 2021 15:05:17
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:09:31
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 17:11:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 17:10:31
Coding entries removed.	Melissa Fuson (b) (4)	03 Nov 2020 17:09:54
	(b) (4)	
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 19:40:24
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

1801 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 19:40:24
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	20 Aug 2020 19:39:10
User entered 'LUMIGAN'	(b) (4), (b) (6)	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'GLAUCOMA'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 14:38:55
User entered '2' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	19 Feb 2021 14:38:39
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Other (OTHER)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'DROP per eye' reason for change:	Andrea Newlands (b) (4)	19 Feb 2021 14:38:55
Data Entry Error	(b) (4)	
User entered 'DROPS' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 14:38:39
User entered 'DROP PER EYE'	(b) (4), (b) (6)	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'once daily (QD)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).		09 Nov 2020 16:21:38
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' answered with 'PER SUBJECT SOURCE EYE DROP IS LISTED AS THE ROUTE OF ADMINISTRATION' (Site from DM).	Melissa Fuson (b) (4)	03 Nov 2020 17:10:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 17:09:54
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 11:25:39
User entered 'Intraocular (INTRAOCULAR)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered 'EYE DROPS' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Nov 2020 17:09:54
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:34:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:38:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:38:45
User entered 'UN Mar 2020'	(b) (4), (b) (6)	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '0'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Yes (Y)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:14
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'		20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:38:45

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:56:27
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 Oct 2020 17:56:27
Data point term sent to Coder	System	09 Oct 2020 17:55:13
User entered 'TYLENOL'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).		28 Jan 2021 10:57:31

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN INJECTION SITE did not meet the AE reporting criteria. ' answered with 'NOTE ON SOURCE DOCUMENTED DATED 21-AUG-2020. SPOKE WITH SUBJECT FOR SAFETY CALL #1 & E-DIRARY. SUBJECT REPORTED PAIN AT INJECTION SITE DAY 1&2 WHICH RESOLVED WITHIN 24 HOURS. TYLENOL WAS TAKEN AS A PREVENTING. NO OTHER COMPLAINTS. THESE WAS A SOLICITED EVEN, NO FURTHER FOLLOW-UP IS INDICATED' (Site from DM).	Melissa Fuson (b) (4)	27 Jan 2021 15:10:29
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:55:37
User entered 'STUDY RELATED INJECTION PAIN'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '500'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered '15 Aug 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '0'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:45:56
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:10
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		15 Oct 2020 20:45:56
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Oct 2020 20:45:43
User entered '15 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:45:43
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:10
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:45:43
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User entered empty.	System	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User entered empty.	System	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:05
User entered empty.	System	09 Oct 2020 17:54:26

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 19:58:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 19:58:27
Data point term sent to Coder	System	09 Oct 2020 17:56:15
User entered 'FLU SHOT'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).		28 Jan 2021 10:57:45
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'UPDATED PROPHYLAXIS TO YES' (Site from DM).	Melissa Fuson (b) (4)	27 Jan 2021 15:11:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 15:10:43
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:55:11
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.		25 Mar 2021 13:42:54
User entered 'INFLUENZA PROPLYXIS'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '0.5'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'mL (mL)'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'once (ONCE)'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered '27 Sep 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '0'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.		25 Mar 2021 13:42:54
User entered '27 Sep 2020'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:00:05
DataPoint Verified.	(b) (4)	25 Mar 2021 13:42:54
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User entered empty.	System	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User entered empty.	System	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:13
User entered empty.	System	09 Oct 2020 17:55:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User closed query 'Please add all con meds per hospital records: IV FENTANYL 100 mCg IV (3/2 19:00), 100 mCg (3/2 19:51), 50 mCg (3/2 11:00) IV HYDROMORPHINE 0.5 mg prn 3/2 – 3/2 (3 doses) ACETAMINOPHEN 1000 mg q 8 hrs DOCUSATE-SENNA 50/8.6 mg 2tabs BID 3/3/21 – OXYCODONE 5m q6 hrs' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:20:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
Query 'Please add all con meds per hospital records: IV FENTANYL 100 mCg IV (3/2 19:00), 100 mCg (3/2 19:51), 50 mCg (3/2 11:00) IV HYDROMORPHINE 0.5 mg prn 3/2 – 3/2 (3 doses) ACETAMINOPHEN 1000 mg q 8 hrs DOCUSATE-SENNA 50/8.6 mg 2tabs BID 3/3/21 – OXYCODONE 5m q6 hrs' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 13:50:54
User opened query 'Please add all con meds per hospital records: IV FENTANYL 100 mCg IV (3/2 19:00), 100 mCg (3/2 19:51), 50 mCg (3/2 11:00) IV HYDROMORPHINE 0.5 mg prn 3/2 – 3/2 (3 doses) ACETAMINOPHEN 1000 mg q 8 hrs DOCUSATE-SENNA 50/8.6 mg 2tabs BID 3/3/21 – OXYCODONE 5m q6 hrs' (Site from CRA).		25 Mar 2021 14:03:59
DataPoint Verified.		25 Mar 2021 13:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 16:28:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 16:28:52
Data point term sent to Coder	System	05 Mar 2021 16:27:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

1857 of 2122

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Gabapentin'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'Cervical spondylosis'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '300'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Steven Anderson (b) (4)	05 Mar 2021 16:27:18
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'three times daily (TID)'	Steven Anderson (b) (4)	05 Mar 2021 16:27:18
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	05 Mar 2021 16:27:18
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '2 Mar 2021'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered '0'	Steven Anderson (b) (4)	05 Mar 2021 16:27:18
	(b) (4)	

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:54
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 16:27:18

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
Data point term sent to Coder	System	14 Apr 2021 14:19:18
Data point term sent to Coder	System	13 Apr 2021 13:42:18
User entered 'TV FENTANYL'	(b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:18:44
User entered 'Spinal cord contusion'		13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '100'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Apr 2021 14:18:44
reason for change: Data Entry Error		
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'		13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User entered empty.	System	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User entered empty.	System	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:18
User entered empty.	System	13 Apr 2021 13:41:27

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
Data point term sent to Coder	System	14 Apr 2021 14:19:18
Data point term sent to Coder	System	13 Apr 2021 13:43:19
User entered 'TV FENTANYL'	(b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:18:53
User entered 'spinal cord contusion'		13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '100'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User entered empty.	System	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User entered empty.	System	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:30
User entered empty.	System	13 Apr 2021 13:43:19

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
Data point term sent to Coder	System	14 Apr 2021 14:19:18
Data point term sent to Coder	System	13 Apr 2021 13:44:28
User entered 'TV FENTANYL'	(b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:19:03
User entered 'spinal cord contusion'		13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '50'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	13 Apr 2021 13:44:21
User entered '02 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:44:21
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Apr 2021 13:44:11
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User entered empty.	System	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User entered empty.	System	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:36
User entered empty.	System	13 Apr 2021 13:44:11

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 08:53:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:53:50
Data point term sent to Coder	System	14 Apr 2021 14:20:20
Data point term sent to Coder	System	13 Apr 2021 13:46:31
User entered 'TV HYDROMORPHONE'	(b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:19:31
User entered 'spinal cord contusion'		13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0.5'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'subject received 3 doses as needed'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User entered empty.	System	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User entered empty.	System	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:03:42
User entered empty.	System	13 Apr 2021 13:45:50

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
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.	(b) (4) Coder Import (b) (4)	14 Apr 2021 14:20:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:20:49
Data point term sent to Coder	System	14 Apr 2021 14:20:19
Coding entries removed.	(b) (4), (b) (6)	14 Apr 2021 14:19:23
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)	13 Apr 2021 13:49:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:49:06
Data point term sent to Coder	System	13 Apr 2021 13:48:33
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:19:23
User entered 'spinal cord contusion'		13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '1000'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:47:44

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENNA ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE;SENNA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 08:52:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:52:42
Data point term sent to Coder	System	14 Apr 2021 14:20:20
Coding entries removed.	(b) (4), (b) (6)	14 Apr 2021 14:19:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENNA ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE;SENNA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:12:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:12:49
Data point term sent to Coder	System	13 Apr 2021 13:49:34
User entered 'DOCUSATE-SENNA'	(b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:49:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 13:49:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:49:04
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:48:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:19:44
User entered 'spinal cord contusion'		13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '50/8.6'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:48:52

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:30:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:30:59
Data point term sent to Coder	System	14 Apr 2021 14:20:19
Coding entries removed.	(b) (4), (b) (6)	14 Apr 2021 14:20:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
Data point term sent to Coder	System	13 Apr 2021 13:50:34
User entered 'OXYCODONE'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:20:18
User entered 'spinal cord contusion'		13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '5'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:50:12

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:23:50
User entered 'Yes (Y)' reason for change: Data Entry Error		14 Apr 2021 14:23:50
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:21
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Mar 2021 16:25:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Mar 2021 16:25:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:32:55

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:25:28

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'WEAR ASPEN COLLAR'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:25:28

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:25:28

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:25:28

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:26:31

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'XR SPINE CERVICAL AP AND LATeral' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:31:48
User entered 'XR spine cervical AP and lat'		14 Apr 2021 14:26:31

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:26:31

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:26:31

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:27:49

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'CT head w/o IV contrast'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:27:49

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:27:49

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:27:49

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:28:36

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'CT trauma CTA neck/cervical spine'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:28:36

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:28:36

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:28:36

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:29:22

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'CT chest w/ IV contrast'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:29:22

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:29:22

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:29:22

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:11

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'CT ABD/pelvis w/IV contrast dual/triple phase'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:11

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:11

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:11

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:46

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'POC US fast abdominal'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:46

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:46

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:30:46

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:31:24

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'MRI cervical spine without contrast'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:31:24

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:31:24

US3412246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:31:24

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'USA-US061-2021-MRNA-1273-P301000013'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Richard'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gregory'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Powell'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gottschlich'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '4260 Glendale Milford Road'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Cincinnati'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered 'OH'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '45242'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered 'US'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 16:07:26
User entered '3'	System	24 Mar 2021 18:06:14
User entered '2'	System	17 Mar 2021 14:31:20
User entered '1'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'USA-US061-2021-MRNA-1273-P301000013'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Richard'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gregory'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Powell'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gottschlich'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '4260 Glendale Milford Road'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Cincinnati'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered 'OH'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '45242'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered 'US'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 16:07:26
User entered '3'	System	24 Mar 2021 18:06:14
User entered '2'	System	17 Mar 2021 14:31:20
User entered '1'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
User entered '08/Mar/2021 17:18'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:58

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.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered '1'		08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'USA-US061-2021-MRNA-1273-P301000013'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Richard'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gregory'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Powell'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gottschlich'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '4260 Glendale Milford Road'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Cincinnati'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered 'OH'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '45242'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered 'US'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 16:07:26
User entered '3'	System	24 Mar 2021 18:06:14
User entered '2'	System	17 Mar 2021 14:31:20
User entered '1'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
User entered '17/Mar/2021 10:31'	System	17 Mar 2021 14:31:20

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:58

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.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered '1'		17 Mar 2021 14:31:20

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'USA-US061-2021-MRNA-1273-P301000013'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Richard'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gregory'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Powell'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gottschlich'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '4260 Glendale Milford Road'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Cincinnati'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered 'OH'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '45242'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered 'US'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 16:07:26
User entered '3'	System	24 Mar 2021 18:06:14
User entered '2'	System	17 Mar 2021 14:31:20
User entered '1'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
User entered '24/Mar/2021 11:06'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:58

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.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered '1'		24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'USA-US061-2021-MRNA-1273-P301000013'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'Yes (Y)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		08 Mar 2021 17:18:03
User entered 'No (N)'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Richard'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gregory'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered 'Powell'	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Gottschlich'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '4260 Glendale Milford Road'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4)	14 Apr 2021 16:07:16
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered 'Cincinnati'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
User entered 'OH'	System	24 Mar 2021 18:06:14

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:16
DataPoint Verified.		25 Mar 2021 13:42:13
Un-reviewed for Safety.	System	24 Mar 2021 18:06:14
User entered empty.	System	24 Mar 2021 18:06:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:18:03
User entered '45242'	System	08 Mar 2021 17:14:39

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:42:13
Reviewed for Safety.		17 Mar 2021 14:31:10
User entered 'US'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 16:07:26
User entered '3'	System	24 Mar 2021 18:06:14
User entered '2'	System	17 Mar 2021 14:31:20
User entered '1'	System	08 Mar 2021 17:18:08

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered '14/Apr/2021 12:07'	(b) (4) System	14 Apr 2021 16:07:26

US3412246

Folder: SAE USA-US061-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:58

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.	Richard Powell (b) (4)	16 Apr 2021 14:51:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:07:26