

US3222299 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:06:41

All time stamps listed in this document are displayed in GMT

US3222299

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

[Participant ID](#)

US3222299

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

US3222299

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3222299

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input 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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3222299

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	23 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

US3222299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3222299

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Were any significant conditions reported?

Yes ☒
No ☐

US3222299

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222299

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Condition	OSTEOARTHRITIS-RIGHT TOE
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	10 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

US3222299

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:50 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 14:50
Height (<i>xxx.x</i>)	165.1 cm
Weight (<i>xxx.x</i>)	59.9 kg
BMI (<i>xxx.x</i>)	21.97519 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)	

US3222299

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 AUG 2020

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

US3222299

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*) 23 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

US3222299

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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 True

Resides in Nursing Home or Assisted Living Facility False

US3222299

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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)	False
Other	False
Specify	

US3222299

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

What was the date of randomization? (dd MMM yyyy) 23 AUG 2020

What was the participant's randomization number? 107627

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 ☒

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Height	ND - Not Done
Weight	ND - Not Done

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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)	23 AUG 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 14:40
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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)	23 AUG 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 16:16
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3222299

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 AUG 2020

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

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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) 23 AUG 2020

What was the treatment time? (00:00-23:59) 15:41 (24 HR)

Treatment Date and Time (derived) 23 AUG 2020 15:41

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

US3222299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 AUG 2020

Collection time (00:00-23:59)

15:19 (24 HR)

Collection date and time (derived)

23 AUG 2020 15:19

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Collection date (dd MMM yyyy)			23 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	23 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

US3222299

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 16:18

PC Open Date & Time

23 AUG 2020 16:01

PC Close Date & Time

23 AUG 2020 18:31

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	23 AUG 2020 19:27
PC Open Date & Time	23 AUG 2020 19:26
PC Close Date & Time	24 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 16:56

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

98.0 °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

25 AUG 2020 18:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

97.4 °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

26 AUG 2020 22:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

97.4 °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

27 AUG 2020 17:54

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

23 AUG 2020 16:19

PC Open Date & Time

23 AUG 2020 16:01

PC Close Date & Time

23 AUG 2020 18:31

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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)

3

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

23 AUG 2020 19:29

PC Open Date & Time

23 AUG 2020 19:26

PC Close Date & Time

24 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 16:56

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

25 AUG 2020 18:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 22:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

27 AUG 2020 17:54

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

29 AUG 2020 19:38

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 16:19
PC Open Date & Time	23 AUG 2020 16:01
PC Close Date & Time	23 AUG 2020 18:31

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 19:29
PC Open Date & Time	23 AUG 2020 19:26
PC Close Date & Time	24 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

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 ☒

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 16:57
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

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)

47 of 2054

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:46
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 22:33
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 17:55
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

53 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2054

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:39
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 31 AUG 2020 06:22

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 31 AUG 2020 16:33

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp 02 SEP 2020 05:59

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 06:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 16:34
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 05:59
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3222299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:38:41

Generated On: 09 Jun 2021 16:06:41

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)	23 SEP 2020
Time of assessment (00:00-23:59)	07:27 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 07:27
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:38:41

Generated On: 09 Jun 2021 16:06:41

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3222299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 08:29 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 08:29

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

US3222299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

07:35 (24 HR)

Collection date and time (derived)

23 SEP 2020 07:35

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:39	23 SEP 2020 07:39
Nasopharyngeal Swab 2	No		

US3222299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 08:54

PC Open Date & Time

23 SEP 2020 08:49

PC Close Date & Time

23 SEP 2020 11:19

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	23 SEP 2020 12:17
PC Open Date & Time	23 SEP 2020 12:14
PC Close Date & Time	24 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

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	98.0 °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	25 SEP 2020 07:14
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

97.6 °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

26 SEP 2020 09:56

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 07:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

27 SEP 2020 12:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

97.4 °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

28 SEP 2020 14:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:44

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 08:55

PC Open Date & Time

23 SEP 2020 08:49

PC Close Date & Time

23 SEP 2020 11:19

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

23 SEP 2020 17:10

PC Open Date & Time

23 SEP 2020 12:14

PC Close Date & Time

24 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

25 SEP 2020 07:14

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

26 SEP 2020 09:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

27 SEP 2020 07:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

27 SEP 2020 12:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

28 SEP 2020 14:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

29 SEP 2020 12:44

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 08:49

PC Close Date & Time

23 SEP 2020 11:19

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 06:39
PC Open Date & Time	23 SEP 2020 12:14
PC Close Date & Time	24 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

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 ☒

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 07:15
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

99 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 09:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

101 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 07:24
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

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 ☒

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

105 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:26
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

107 of 2054

EAB) (1725)

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:44
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3222299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:39:29

Generated On: 09 Jun 2021 16:06:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:39:29

Generated On: 09 Jun 2021 16:06:41

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) _____

US3222299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:39:29

Generated On: 09 Jun 2021 16:06:41

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.

US3222299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:38:41

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	07:38 (24 HR)
Collection date and time (derived)	21 OCT 2020 07:38

US3222299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:41

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 06:28:42
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

02 NOV 2020 17:44:47

Patient Cloud Open Date & Time

30 OCT 2020 00:01

Patient Cloud Close Date & Time

03 NOV 2020 23:59

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

10 NOV 2020 11:59:19

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <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"/>

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 12:02:42
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

05 DEC 2020 12:05:56

Patient Cloud Open Date & Time

01 DEC 2020 00:01

Patient Cloud Close Date & Time

05 DEC 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 01:18:57
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

17 DEC 2020 12:00:36

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 DEC 2020 04:57:54
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 DEC 2020 00:08:06
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 12:03:50
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 09:40:02
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 12:00:38
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 13:42:53
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 05:47:09
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

12 FEB 2021 17:53:37

Patient Cloud Open Date & Time

09 FEB 2021 00:01

Patient Cloud Close Date & Time

13 FEB 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 17:59:22
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

25 FEB 2021 17:00:26

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 12:01:00
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

11 MAR 2021 12:00:28

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 18:52:09

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

25 MAR 2021 12:00:34

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 12:00:27

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

08 APR 2021 12:19:09

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

15 APR 2021 12:00:36

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:21:11

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

29 APR 2021 12:00:26

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

25 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 285

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

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

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

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

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

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

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

08 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2021 00:01
Patient Cloud Close Date & Time	03 JUL 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	10 JUL 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2021 00:01
Patient Cloud Close Date & Time	24 JUL 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2021 00:01
Patient Cloud Close Date & Time	31 JUL 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

10 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

17 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

07 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2021 00:01
Patient Cloud Close Date & Time	18 SEP 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

28 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

Patient Cloud Open Date & Time	05 OCT 2021 00:01
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Patient Cloud Close Date & Time	09 OCT 2021 23:59
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US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2021 00:01
Patient Cloud Close Date & Time	16 OCT 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

19 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

Patient Cloud Open Date & Time	26 OCT 2021 00:01
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Patient Cloud Close Date & Time	30 OCT 2021 23:59
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US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

16 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 DEC 2021 00:01
Patient Cloud Close Date & Time	01 JAN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

11 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JAN 2022 00:01
Patient Cloud Close Date & Time	29 JAN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

01 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

15 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

01 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

08 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

15 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

22 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

29 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

19 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 APR 2022 00:01
Patient Cloud Close Date & Time	30 APR 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

10 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2022 00:01
Patient Cloud Close Date & Time	25 JUN 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

28 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

19 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2022 00:01
Patient Cloud Close Date & Time	30 JUL 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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="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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

Patient Cloud Open Date & Time	16 AUG 2022 00:01
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Patient Cloud Close Date & Time	20 AUG 2022 23:59
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US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

06 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

20 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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 <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"/>

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2022 23:59

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2022 23:59

US3222299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:06:41

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		04 MAR 2021 12:01:08

US3222299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:38:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:06:41

Generated On: 09 Jun 2021 16:06:41

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

Visit date (dd MMM yyyy)	31 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:06:41

Generated On: 09 Jun 2021 16:06:41

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) _____

US3222299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:06:40

Generated On: 09 Jun 2021 16:06:41

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.

US3222299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:06:40

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

31 MAR 2021 14:25

US3222299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:06:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:06:40

Generated On: 09 Jun 2021 16:06:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222299

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:06:40

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222299

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222299

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:06:41

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"/>

US3222299

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:06:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222299

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:05:00

Generated On: 09 Jun 2021 16:06:41

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

Visit date (dd MMM yyyy)	31 MAR 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3222299

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:05:00

Generated On: 09 Jun 2021 16:06:41

Date of updated informed consent (dd MMM yyyy) 31 MAR 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) 5 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 _____

US3222299

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:05:00

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	31 MAR 2021 14:25

US3222299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 14:05:00

Generated On: 09 Jun 2021 16:06:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00 - 23:59)	14:27
Collection Date and Time (derived)	31 MAR 2021 14:27

US3222299

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:04:57

Generated On: 09 Jun 2021 16:06:41

AEID	USA-US104-2020-MRNA-1273-P30 1000010
Adverse event	SMALL BOWEL OBSTRUCTION
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)	3 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	5 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

331 of 2054

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:04:57

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:04:57

Generated On: 09 Jun 2021 16:06:41

DURING SUBJECTS DAY 43
SAFETY CALL @ 11:23
07/OCT/2020 I FOUND OUT SHE
WENT INTO THE HOSPITAL ON
03/OCT/2020 FOR STOMACH
DISCOMFORT. SAME DAY OF
ADMISSION SHE WAS
DIAGNOSED WITH HAVING A
SMALL BOWEL OBSTRUCTION
AFTER HAVING A CT OF THE
ABDOMEN AND PELVIS
SHOWED A SMALL BOWEL
OBSTRUCTION AT THE MID
ILEUM WHERE LOOK OF
SMALL BOWEL WAS FOUND TO
BE HERNIATED THROUGH
OMENTUM. POST OPERATIVE.
XRAY ABDOMEN VERIFIED CT
RESULTS.
03/OCT/2020 POST OPERATIVE
XRAY SHOWED
NONOBSTRUCTIVE BOWEL GAS
PATTERNS.

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

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:04:57

Generated On: 09 Jun 2021 16:06:41

AEID

Adverse event

INJECTION SITE PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 AUG 2020

Start time (00:00-23:59)

19:29 (24 HR)

AE start date and time (derived)

23 AUG 2020 19:29

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 AUG 2020

End time (00:00-23:59)

16:33 (24 HR)

AE End Date and Time (derived)

31 AUG 2020 16:33

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

334 of 2054

EAB) (1725)

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:04:57

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 14:05:00

Generated On: 09 Jun 2021 16:06:41

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

Yes ☒

No ☐

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

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

337 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication GENERAL PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

339 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 5 OCT 2020		
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication ACETAMINOPHEN-OXYCODON
E

Prophylaxis Yes ☒
No ☐

Indication GENERAL PAIN

Dose per administration 325

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)

341 of 2054

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication D5 1/S NORMAL SALINE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2054

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN SECONDARY
TO SMALL BOWEL
OBSTRUCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

345 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication MORPHINE

Prophylaxis Yes ☒
No ☐

Indication GENERAL PAIN

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

EVERY 4 HOURS, PRN

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

PRODUCTION RELEASE (v12.003

347 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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 4 HOURS, PRN

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

PRODUCTION RELEASE (v12.003

349 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

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

EVERY 12 HOURS

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

PRODUCTION RELEASE (v12.003

351 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 5 OCT 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"/>	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

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

PRN

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

PRODUCTION RELEASE (v12.003

353 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication ZOSYN
(PIPERACILLIN-TAZOBACTAM)

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2054

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 OCT 2020
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"/>

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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

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

PRODUCTION RELEASE (v12.003

357 of 2054

EAB) (1725)

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:04:58

Generated On: 09 Jun 2021 16:06:41

	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)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 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"/>

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
4 OCT 2020	EXPLORATORY LAPAROTOMY	Diagnostic	
03 OCT 2020	CAT SCAN OF ABDOMEN AND PELVIS	Adverse Event	
03 OCT 2020	X-RAY ABDOMEN FLAT/UPRIGHT WITH CHEST	Adverse Event	

US3222299

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:06:41

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

US3222299

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:06:41

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 ☐

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 12:57
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

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/OCT/2020 15:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/NOV/2020 11:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/NOV/2020 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Data signed: (b) (4) 20 Feb 2021 14:38:39

Generated On: 09 Jun 2021 16:06:41

SAEID	USA-US104-2020-MRNA-1273-P301000010
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	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/DEC/2020 09:37
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

US3222299 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222299

Form: Participant Creation

Generated On: 09 Jun 2021 16:06:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'US3222299'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:19:11

US3222299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:01

US3222299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:19:12

US3222299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:01

US3222299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'SCRN'	System	23 Aug 2020 19:48:01

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:19:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '57'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'YEARS'	System	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '57'	System	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Female (F)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'I'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4)	
	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13
	(b) (4)	

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:13

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered '23 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'Aug 2020'	System	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '2020'	System	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:48:10

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:32:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:19:12

US3222299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'I'	System	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:06:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:49:36

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:50:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:50:36
Data point term sent to Coder	System	24 Aug 2020 15:50:16
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'I'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered empty.	System	24 Aug 2020 15:49:53

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Toe osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:56:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:56:07
Data point term sent to Coder	System	16 Oct 2020 17:40:47
User entered 'Osteoarthritis-right toe'	Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'un UNK 1998'	Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '10 Sep 2020'	Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'Jan 1998'	System	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '1998'	System	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'Sep 2020'	System	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '2020'	System	16 Oct 2020 17:40:06

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4)	
	Amber Vasquez (b) (4)	24 Aug 2020 15:51:34
	(b) (4)	

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	Amber Vasquez (b) (4)	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '14:50'	Amber Vasquez (b) (4)	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '23 Aug 2020 14:50'	System	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '165.1' cm	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:51:34
DataPoint set to visible.	(b) (4) System	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '59.9' kg	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:51:34
DataPoint set to visible.	(b) (4) System	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
Amendment Manager: User entered '21.97519'	System	17 Sep 2020 00:20:33
User entered '22.0'	System	24 Aug 2020 15:51:34
DataPoint set to visible.	System	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'kg/m2'	System	24 Aug 2020 15:51:34
DataPoint set to visible.	System	23 Aug 2020 19:48:15

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 20:02:55
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:08:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:08:21
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 15:36:48
User entered '37.2' C	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	20 Sep 2020 21:08:21
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:21
User entered '61'	Albert Garcia (b) (4)	24 Aug 2020 15:51:34
	(b) (4)	

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'bpm'	System	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:21
User entered '16'	Albert Garcia (b) (4)	24 Aug 2020 15:51:34
	(b) (4)	

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'breaths/min'	System	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:21
User entered '115'	Albert Garcia (b) (4)	24 Aug 2020 15:51:34
	(b) (4)	

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'mmHg'	System	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:21
User entered '83'	Albert Garcia (b) (4)	24 Aug 2020 15:51:34
	(b) (4)	

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered 'mmHg'	System	24 Aug 2020 15:51:34

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21

US3222299

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:51:45

US3222299

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	Amber Vasquez (b) (4)	24 Aug 2020 15:51:45

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:06:41

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'I'	Amber Vasquez (b) (4)	24 Aug 2020 15:52:48

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '0'	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 15:53:29

US3222299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:54:02

US3222299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:54:02

US3222299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Clinic (Clinic)'	Amber Vasquez (b) (4)	24 Aug 2020 15:54:02

US3222299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'VISIT1'	System	24 Aug 2020 15:54:02

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:24:09

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '107627'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:24:09

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 19:24:09

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:26:01
Query ' PER CDM: Please complete this section of the form' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:08:51
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:08:46
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:37:14

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Sep 2020 21:08:46

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:08:46

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:08:46

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:08:46

US3222299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:08:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:23:19

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '165.1' cm	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '59.9' kg	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '165.1' cm	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '59.9' kg	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '14:40'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Aug 2020 14:40'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '37.2' C	Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '61'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'bpm'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '18'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'breaths/min'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '123'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '80'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '165.1' cm	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:08:00
User entered '59.9' kg	Albert Garcia (b) (4)	24 Aug 2020 15:57:25
	(b) (4)	

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '16:16'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Aug 2020 16:16'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Aug 2020 15:57:35
User entered '36.7' C reason for change: Data Entry Error	System	24 Aug 2020 15:57:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Amber Vasquez (b) (4)	24 Aug 2020 15:57:25
User entered '36.7' (non-conformant).	(b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '60'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'bpm'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '14'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'breaths/min'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '120'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '84'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	24 Aug 2020 15:57:25

US3222299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:57:45

US3222299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	Amber Vasquez (b) (4)	24 Aug 2020 15:57:45

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'MRNA-1273 OR PLACEBO'	System	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '15:41'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Aug 2020 15:41'	System	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'ONCE'	System	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'INTRAMUSCULAR'	System	23 Aug 2020 19:48:58

US3222299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:58:03

US3222299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:58:03

US3222299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '15:19'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:58:03

US3222299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Aug 2020 15:19'	System	24 Aug 2020 15:58:03

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '15:20'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Aug 2020 15:20'	System	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	24 Aug 2020 15:58:22

US3222299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 15:59:13

US3222299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	24 Aug 2020 15:59:13

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:18:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '48e0d234-024e-4323-a449-9a2baab77015' User entered 'Yes (Y)'	System	23 Aug 2020 20:18:53
	System	23 Aug 2020 20:18:53

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:18:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '48e0d234-024e-4323-a449-9a2baab77015' User entered '98.0'	System	23 Aug 2020 20:18:53
	System	23 Aug 2020 20:18:53

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:18:45', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '48e0d234-024e-4323-a449-9a2baab77015'	System	23 Aug 2020 20:18:53
User entered 'No (N)'	System	23 Aug 2020 20:18:53

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:18:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '48e0d234-024e-4323-a449-9a2baab77015' User entered '23 Aug 2020 16:18'	System	23 Aug 2020 20:18:53
	System	23 Aug 2020 20:18:53

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 16:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 18:31'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b0ff00f8-7313-4444-b111-b6ba2e3fdaa1' User entered 'Yes (Y)'	System	23 Aug 2020 23:27:48
	System	23 Aug 2020 23:27:48

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b0ff00f8-7313-4444-b111-b6ba2e3fdaa1' User entered '98.0'	System	23 Aug 2020 23:27:48
	System	23 Aug 2020 23:27:48

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b0ff00f8-7313-4444-b111-b6ba2e3fdaa1'	System	23 Aug 2020 23:27:48
User entered 'No (N)'	System	23 Aug 2020 23:27:48

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:46', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b0ff00f8-7313-4444-b111-b6ba2e3fdaa1' User entered '23 Aug 2020 19:27'	System	23 Aug 2020 23:27:48
	System	23 Aug 2020 23:27:48

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 19:26'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 2'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:12', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '67ec956a-4ed4-4db9-b4c5-37f4c23e2a77' User entered 'Yes (Y)'	System	24 Aug 2020 20:56:36
	System	24 Aug 2020 20:56:36

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:26', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '67ec956a-4ed4-4db9-b4c5-37f4c23e2a77' User entered '97.9'	System	24 Aug 2020 20:56:36
	System	24 Aug 2020 20:56:36

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '67ec956a-4ed4-4db9-b4c5-37f4c23e2a77'	System	24 Aug 2020 20:56:36
User entered 'No (N)'	System	24 Aug 2020 20:56:36

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '67ec956a-4ed4-4db9-b4c5-37f4c23e2a77'	System	24 Aug 2020 20:56:36
User entered '24 Aug 2020 16:56'	System	24 Aug 2020 20:56:36

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 3'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:44:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0e4d892e-285e-4f2d-bc13-7e5d9d278a37' User entered 'Yes (Y)'	System	25 Aug 2020 22:45:05
	System	25 Aug 2020 22:45:05

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:44:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0e4d892e-285e-4f2d-bc13-7e5d9d278a37' User entered '98.0'	System	25 Aug 2020 22:45:05
	System	25 Aug 2020 22:45:05

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:44:59', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0e4d892e-285e-4f2d-bc13-7e5d9d278a37'	System	25 Aug 2020 22:45:05
User entered 'No (N)'	System	25 Aug 2020 22:45:05

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:03', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0e4d892e-285e-4f2d-bc13-7e5d9d278a37' User entered '25 Aug 2020 18:45'	System	25 Aug 2020 22:45:05
	System	25 Aug 2020 22:45:05

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 4'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:18', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7f7df162-720b-49c7-af55-c7428487d41f' User entered 'Yes (Y)'	System	27 Aug 2020 02:32:39
	System	27 Aug 2020 02:32:39

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:23', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7f7df162-720b-49c7-af55-c7428487d41f' User entered '97.4'	System	27 Aug 2020 02:32:39
	System	27 Aug 2020 02:32:39

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7f7df162-720b-49c7-af55-c7428487d41f' User entered 'No (N)'	System	27 Aug 2020 02:32:39
	System	27 Aug 2020 02:32:39

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7f7df162-720b-49c7-af55-c7428487d41f' User entered '26 Aug 2020 22:32'	System	27 Aug 2020 02:32:39
	System	27 Aug 2020 02:32:39

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 5'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:53:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0962e864-5dfd-4ddd-8747-289991d4e260' User entered 'Yes (Y)'	System	27 Aug 2020 21:54:17
	System	27 Aug 2020 21:54:17

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0962e864-5dfd-4ddd-8747-289991d4e260' User entered '97.4'	System	27 Aug 2020 21:54:17
	System	27 Aug 2020 21:54:17

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:10', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0962e864-5dfd-4ddd-8747-289991d4e260'	System	27 Aug 2020 21:54:17
User entered 'No (N)'	System	27 Aug 2020 21:54:17

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:14', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '0962e864-5dfd-4ddd-8747-289991d4e260'	System	27 Aug 2020 21:54:17
User entered '27 Aug 2020 17:54'	System	27 Aug 2020 21:54:17

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 6'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 7'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:07', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '01bb7989-a2e9-4dd7-b302-3a1d19a06894' User entered 'Yes (Y)'	System	29 Aug 2020 23:39:19
	System	29 Aug 2020 23:39:19

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:12', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '01bb7989-a2e9-4dd7-b302-3a1d19a06894' User entered '97.2'	System	29 Aug 2020 23:39:19
	System	29 Aug 2020 23:39:19

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:14', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '01bb7989-a2e9-4dd7-b302-3a1d19a06894'	System	29 Aug 2020 23:39:19
User entered 'No (N)'	System	29 Aug 2020 23:39:19

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '01bb7989-a2e9-4dd7-b302-3a1d19a06894' User entered '29 Aug 2020 19:39'	System	29 Aug 2020 23:39:19
	System	29 Aug 2020 23:39:19

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:15:12', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a49808f5-116a-4012-babc-e8352d65c676' User entered 'None (1)'	System	23 Aug 2020 20:19:06
	System	23 Aug 2020 20:19:06

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:15:16', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a49808f5-116a-4012-babc-e8352d65c676' User entered 'No (N)'	System	23 Aug 2020 20:19:06
	System	23 Aug 2020 20:19:06

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:15:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a49808f5-116a-4012-babc-e8352d65c676' User entered 'No (N)'	System	23 Aug 2020 20:19:06
	System	23 Aug 2020 20:19:06

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a49808f5-116a-4012-babc-e8352d65c676' User entered 'None (1)'	System	23 Aug 2020 20:19:06
	System	23 Aug 2020 20:19:06

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:03', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a49808f5-116a-4012-babc-e8352d65c676' User entered '23 Aug 2020 16:19'	System	23 Aug 2020 20:19:06
	System	23 Aug 2020 20:19:06

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 16:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 18:31'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:53', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923'	System	23 Aug 2020 23:29:11
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:27:56', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923' User entered 'No (N)'	System	23 Aug 2020 23:29:11
	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:28:09', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923' User entered 'Yes (Y)'	System	23 Aug 2020 23:29:11
	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:28:59', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923' User entered '3'	System	23 Aug 2020 23:29:11
	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923' User entered 'None (1)'	System	23 Aug 2020 23:29:11
	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:07', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b3652140-b601-4761-80e8-af72ec377923' User entered '23 Aug 2020 19:29'	System	23 Aug 2020 23:29:11
	System	23 Aug 2020 23:29:11

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 19:26'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 2'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:45', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered 'No (N)'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:48', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered 'Yes (Y)'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:51', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered '2'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered 'None (1)'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:56:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e8119cd2-b0c8-45b5-8c19-8584b2ac606f' User entered '24 Aug 2020 16:56'	System	24 Aug 2020 20:57:03
	System	24 Aug 2020 20:57:03

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 3'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '786094ab-022b-4ca2-aa44-407797e5d58c' User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 22:45:37
	System	25 Aug 2020 22:45:37

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '786094ab-022b-4ca2-aa44-407797e5d58c' User entered 'No (N)'	System	25 Aug 2020 22:45:37
	System	25 Aug 2020 22:45:37

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:26', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '786094ab-022b-4ca2-aa44-407797e5d58c' User entered 'No (N)'	System	25 Aug 2020 22:45:37
	System	25 Aug 2020 22:45:37

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:30', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '786094ab-022b-4ca2-aa44-407797e5d58c' User entered 'None (1)'	System	25 Aug 2020 22:45:37
	System	25 Aug 2020 22:45:37

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '786094ab-022b-4ca2-aa44-407797e5d58c' User entered '25 Aug 2020 18:45'	System	25 Aug 2020 22:45:37
	System	25 Aug 2020 22:45:37

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 4'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered 'No (N)'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:32:57', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered 'Yes (Y)'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:03', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered '2'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered 'None (1)'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:08', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1364ccfa-55a6-4e22-984b-07afefe12ae1' User entered '26 Aug 2020 22:33'	System	27 Aug 2020 02:33:22
	System	27 Aug 2020 02:33:22

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 5'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:21', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '77b39b4f-6be0-4832-abfc-08956584544d' User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 21:54:39
	System	27 Aug 2020 21:54:39

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '77b39b4f-6be0-4832-abfc-08956584544d' User entered 'No (N)'	System	27 Aug 2020 21:54:39
	System	27 Aug 2020 21:54:39

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:26', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '77b39b4f-6be0-4832-abfc-08956584544d' User entered 'No (N)'	System	27 Aug 2020 21:54:39
	System	27 Aug 2020 21:54:39

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '77b39b4f-6be0-4832-abfc-08956584544d' User entered 'None (1)'	System	27 Aug 2020 21:54:39
	System	27 Aug 2020 21:54:39

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:36', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '77b39b4f-6be0-4832-abfc-08956584544d' User entered '27 Aug 2020 17:54'	System	27 Aug 2020 21:54:39
	System	27 Aug 2020 21:54:39

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 6'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 7'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:38:45', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7c8d6845-3f0b-45b6-9d6c-65557254c1bb' User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 23:38:58
	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:38:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7c8d6845-3f0b-45b6-9d6c-65557254c1bb' User entered 'No (N)'	System	29 Aug 2020 23:38:58
	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:38:49', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7c8d6845-3f0b-45b6-9d6c-65557254c1bb' User entered 'No (N)'	System	29 Aug 2020 23:38:58
	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:38:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7c8d6845-3f0b-45b6-9d6c-65557254c1bb' User entered 'None (1)'	System	29 Aug 2020 23:38:58
	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:38:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7c8d6845-3f0b-45b6-9d6c-65557254c1bb' User entered '29 Aug 2020 19:38'	System	29 Aug 2020 23:38:58
	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:08', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:11', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:16', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:21', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'None (0)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered 'No (N)'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T16:19:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '3f121ce8-a6e2-4e03-84ce-7bbf27d3c920' User entered '23 Aug 2020 16:19'	System	23 Aug 2020 20:19:29
	System	23 Aug 2020 20:19:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 16:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 18:31'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:22', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'None (0)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:26', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered 'No (N)'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-23T19:29:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '06e6eaca-8329-4d7c-a999-a34a71d94f7a' User entered '23 Aug 2020 19:29'	System	23 Aug 2020 23:29:33
	System	23 Aug 2020 23:29:33

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Aug 2020 19:26'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 2'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:05', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'None (0)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:09', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'Some interference with activity (2)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'No interference with activity (1)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'No interference with activity (1)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'None (0)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:21', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'None (0)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered 'No (N)'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-24T16:57:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5fbabac8-ff8d-4965-9701-f3f680c08c6b' User entered '24 Aug 2020 16:57'	System	24 Aug 2020 20:57:29
	System	24 Aug 2020 20:57:29

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 3'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered 'None (0)'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3'	System	25 Aug 2020 22:46:02
User entered 'No interference with activity (1)'	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3'	System	25 Aug 2020 22:46:02
User entered 'No interference with activity (1)'	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:51', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered 'None (0)'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:53', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered 'None (0)'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:56', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered 'None (0)'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:45:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered 'No (N)'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-25T18:46:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6b7d2c5b-a639-4e59-adc9-f5cde72e0ed3' User entered '25 Aug 2020 18:46'	System	25 Aug 2020 22:46:02
	System	25 Aug 2020 22:46:02

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 4'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:14', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'None (0)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:18', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'Some interference with activity (2)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:22', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'No interference with activity (1)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'No interference with activity (1)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'None (0)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'None (0)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered 'No (N)'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-26T22:33:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8180484d-4e44-4835-9671-8549e0d9f02f' User entered '26 Aug 2020 22:33'	System	27 Aug 2020 02:33:53
	System	27 Aug 2020 02:33:53

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 5'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:40', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'None (0)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'No interference with activity (1)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'None (0)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:49', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'None (0)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'None (0)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'None (0)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:54:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered 'No (N)'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-27T17:55:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd24502ee-4f1f-4e2b-866e-84868f3aa3cf' User entered '27 Aug 2020 17:55'	System	27 Aug 2020 21:55:05
	System	27 Aug 2020 21:55:05

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 6'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 7'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:21', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:23', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:25', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:28', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:30', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered 'None (0)'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20'	System	29 Aug 2020 23:39:38
User entered 'No (N)'	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-29T19:39:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2ad2df40-b7d1-4ef8-9b21-fd14ba8e2f20' User entered '29 Aug 2020 19:39'	System	29 Aug 2020 23:39:38
	System	29 Aug 2020 23:39:38

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	29 Aug 2020 23:38:58
User entered 'Day 8'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T06:22:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b653b544-9b84-487a-8a3b-853bb4d81eeb'	System	31 Aug 2020 10:22:24
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T06:22:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b653b544-9b84-487a-8a3b-853bb4d81eeb' User entered '31 Aug 2020 06:22'	System	31 Aug 2020 10:22:24
	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	29 Aug 2020 23:38:58
User entered 'Day 9'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T16:33:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8a3cdf0-09fa-418d-9c81-d03fe134356c'	System	31 Aug 2020 20:34:05
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 20:34:05

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T16:33:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8a3cdfe0-09fa-418d-9c81-d03fe134356c' User entered '31 Aug 2020 16:33'	System	31 Aug 2020 20:34:05
	System	31 Aug 2020 20:34:05

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	31 Aug 2020 10:22:24
User entered 'Day 10'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-02T05:59:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9de99492-d521-43ab-b263-52bff8da0ec4' User entered 'None (1)'	System	02 Sep 2020 09:59:41
	System	02 Sep 2020 09:59:41

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-02T05:59:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9de99492-d521-43ab-b263-52bff8da0ec4' User entered '02 Sep 2020 05:59'	System	02 Sep 2020 09:59:41
	System	02 Sep 2020 09:59:41

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	29 Aug 2020 23:38:58
User entered 'Day 8'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T06:22:25', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'ad063133-35da-4227-9fa3-398956f9b0f4'	System	31 Aug 2020 10:22:29
User entered 'No (N)'	System	31 Aug 2020 10:22:29

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T06:22:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'ad063133-35da-4227-9fa3-398956f9b0f4' User entered '31 Aug 2020 06:22'	System	31 Aug 2020 10:22:29
	System	31 Aug 2020 10:22:29

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	29 Aug 2020 23:38:58
User entered 'Day 9'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T16:34:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '89b9a32a-cdf1-4272-98c2-8df665ce0240' User entered 'No (N)'	System	31 Aug 2020 20:34:08
	System	31 Aug 2020 20:34:08

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-08-31T16:34:05', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '89b9a32a-cdf1-4272-98c2-8df665ce0240' User entered '31 Aug 2020 16:34'	System	31 Aug 2020 20:34:08
	System	31 Aug 2020 20:34:08

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 23:38:58

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	31 Aug 2020 10:22:24
User entered 'Day 10'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-02T05:59:40', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8b7bba6f-aa0d-4d60-b1cc-950182b59999' User entered 'No (N)'	System	02 Sep 2020 09:59:47
	System	02 Sep 2020 09:59:47

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-02T05:59:43', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8b7bba6f-aa0d-4d60-b1cc-950182b59999'	System	02 Sep 2020 09:59:47
User entered '02 Sep 2020 05:59'	System	02 Sep 2020 09:59:47

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 10:22:24

US3222299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 10:22:24

US3222299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:31:35

US3222299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 16:23:56
User entered '2 Sep 2020'	(b) (4)	
	Crystal Paccione (b) (4)	23 Sep 2020 12:31:35
	(b) (4)	

US3222299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:31:35

US3222299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:31:35

US3222299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:31:44

US3222299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	23 Sep 2020 12:31:44

US3222299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	23 Sep 2020 12:32:33

US3222299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '09 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 16:24:11
User entered '9 Sep 2020'	Crystal Paccione (b) (4)	23 Sep 2020 12:32:33

US3222299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 12:32:33

US3222299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:32:33

US3222299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:32:49

US3222299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User entered 'I'	System	23 Sep 2020 12:32:49

US3222299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	23 Sep 2020 12:33:14

US3222299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '16 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:14

US3222299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:14

US3222299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:14

US3222299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:20

US3222299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:22
User entered 'I'	System	23 Sep 2020 12:33:20

US3222299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:52

US3222299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:33:52

US3222299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 12:33:52

US3222299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'VISIT2'	System	23 Sep 2020 12:33:52

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '07:27'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Sep 2020 07:27'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '36.6' C	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '64'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'bpm'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '16'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'breaths/min'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '117'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '87'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '09:05'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Sep 2020 09:05'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '36.6' C	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '61'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'bpm'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '16'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'breaths/min'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '131'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '96'	Albert Garcia (b) (4)	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'mmHg'	System	29 Sep 2020 17:46:07

US3222299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:14

US3222299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 17:46:14

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Crystal Paccione (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '08:29'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Sep 2020 08:29'	System	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Left Arm (LEFT ARM)'	Crystal Paccione (b) (4)	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'ONCE'	System	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 12:34:13

US3222299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:34

US3222299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:29:23
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'SAMPLE WAS SHIPPED ACCORDING TO LAB STAFF.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 11:57:11
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:40:31
User entered '23 Sep 2020'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:34

US3222299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '07:35'	Albert Garcia (b) (4)	29 Sep 2020 17:46:34

US3222299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Sep 2020 07:35'	System	29 Sep 2020 17:46:34

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '07:39'	Albert Garcia (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '23 Sep 2020 07:39'	System	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'No (N)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Albert Garcia (b) (4)	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	29 Sep 2020 17:46:47

US3222299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 17:46:51

US3222299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '1'	System	29 Sep 2020 17:46:51

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:54:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'db2c432c-fd57-4916-a80e-705b10e6ba9d' User entered 'Yes (Y)'	System	23 Sep 2020 12:54:47
	System	23 Sep 2020 12:54:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:54:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'db2c432c-fd57-4916-a80e-705b10e6ba9d' User entered '98.0'	System	23 Sep 2020 12:54:47
	System	23 Sep 2020 12:54:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:54:36', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'db2c432c-fd57-4916-a80e-705b10e6ba9d' User entered 'No (N)'	System	23 Sep 2020 12:54:47
	System	23 Sep 2020 12:54:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:54:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'db2c432c-fd57-4916-a80e-705b10e6ba9d' User entered '23 Sep 2020 08:54'	System	23 Sep 2020 12:54:47
	System	23 Sep 2020 12:54:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 08:49'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 11:19'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T12:17:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '854bf5f8-826f-4199-8332-e04dedbf99e7' User entered 'Yes (Y)'	System	23 Sep 2020 16:17:48
	System	23 Sep 2020 16:17:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T12:17:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '854bf5f8-826f-4199-8332-e04dedbf99e7' User entered '97.6'	System	23 Sep 2020 16:17:48
	System	23 Sep 2020 16:17:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T12:17:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '854bf5f8-826f-4199-8332-e04dedbf99e7'	System	23 Sep 2020 16:17:48
User entered 'No (N)'	System	23 Sep 2020 16:17:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T12:17:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '854bf5f8-826f-4199-8332-e04dedbf99e7' User entered '23 Sep 2020 12:17'	System	23 Sep 2020 16:17:48
	System	23 Sep 2020 16:17:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 2'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:13:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered 'Yes (Y)'	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:13:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered '98.0'	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered 'Yes (Y)'	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
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)	02 Nov 2020 16:37:05
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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:07', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered '1'	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:15:48
	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:07', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered '0'	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '55e316ee-b7f0-4e74-b149-626271d83c0c' User entered '25 Sep 2020 07:14'	System	25 Sep 2020 11:14:14
	System	25 Sep 2020 11:14:14

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 3'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:34', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'de1ee8c4-08af-47d3-bcb0-b2ef6586a504' User entered 'Yes (Y)'	System	26 Sep 2020 13:56:47
	System	26 Sep 2020 13:56:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'de1ee8c4-08af-47d3-bcb0-b2ef6586a504' User entered '97.6'	System	26 Sep 2020 13:56:47
	System	26 Sep 2020 13:56:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:40', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'de1ee8c4-08af-47d3-bcb0-b2ef6586a504' User entered 'No (N)'	System	26 Sep 2020 13:56:47
	System	26 Sep 2020 13:56:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'de1ee8c4-08af-47d3-bcb0-b2ef6586a504' User entered '26 Sep 2020 09:56'	System	26 Sep 2020 13:56:47
	System	26 Sep 2020 13:56:47

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 4'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:23:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4929e2c4-055e-4a89-bf0a-f4a1ea09bcd8' User entered 'Yes (Y)'	System	27 Sep 2020 11:24:10
	System	27 Sep 2020 11:24:10

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:23:59', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4929e2c4-055e-4a89-bf0a-f4a1ea09bcd9' User entered '97.7'	System	27 Sep 2020 11:24:10
	System	27 Sep 2020 11:24:10

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4929e2c4-055e-4a89-bf0a-f4a1ea09bcd9' User entered 'No (N)'	System	27 Sep 2020 11:24:10
	System	27 Sep 2020 11:24:10

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:05', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4929e2c4-055e-4a89-bf0a-f4a1ea09bcd9' User entered '27 Sep 2020 07:24'	System	27 Sep 2020 11:24:10
	System	27 Sep 2020 11:24:10

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 5'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '78baeba6-c1bc-4ac7-8cdd-d6736141cdf3' User entered 'Yes (Y)'	System	27 Sep 2020 16:00:48
	System	27 Sep 2020 16:00:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '78baeba6-c1bc-4ac7-8cdd-d6736141cdf3' User entered '97.6'	System	27 Sep 2020 16:00:48
	System	27 Sep 2020 16:00:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '78baeba6-c1bc-4ac7-8cdd-d6736141cdf3' User entered 'No (N)'	System	27 Sep 2020 16:00:48
	System	27 Sep 2020 16:00:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:39', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '78baeba6-c1bc-4ac7-8cdd-d6736141cdf3'	System	27 Sep 2020 16:00:48
User entered '27 Sep 2020 12:00'	System	27 Sep 2020 16:00:48

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 6'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd9caa688-15da-4392-a89d-09fffe538276' User entered 'Yes (Y)'	System	28 Sep 2020 18:25:29
	System	28 Sep 2020 18:25:29

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:20', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd9caa688-15da-4392-a89d-09fffe538276' User entered '97.4'	System	28 Sep 2020 18:25:29
	System	28 Sep 2020 18:25:29

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:23', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd9caa688-15da-4392-a89d-09fffe538276'	System	28 Sep 2020 18:25:29
User entered 'No (N)'	System	28 Sep 2020 18:25:29

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:27', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd9caa688-15da-4392-a89d-09fffe538276' User entered '28 Sep 2020 14:25'	System	28 Sep 2020 18:25:29
	System	28 Sep 2020 18:25:29

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 7'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:01', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a3ca6e61-d51d-49d9-b413-810719a3ff6b' User entered 'Yes (Y)'	System	29 Sep 2020 16:44:21
	System	29 Sep 2020 16:44:21

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:05', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a3ca6e61-d51d-49d9-b413-810719a3ff6b' User entered '97.6'	System	29 Sep 2020 16:44:21
	System	29 Sep 2020 16:44:21

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:12', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a3ca6e61-d51d-49d9-b413-810719a3ff6b' User entered 'No (N)'	System	29 Sep 2020 16:44:21
	System	29 Sep 2020 16:44:21

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'a3ca6e61-d51d-49d9-b413-810719a3ff6b' User entered '29 Sep 2020 12:44'	System	29 Sep 2020 16:44:21
	System	29 Sep 2020 16:44:21

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:55:11', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75027077-7e52-498a-9a25-987ac6512c34' User entered 'None (1)'	System	23 Sep 2020 12:55:24
	System	23 Sep 2020 12:55:24

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:55:14', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75027077-7e52-498a-9a25-987ac6512c34' User entered 'No (N)'	System	23 Sep 2020 12:55:24
	System	23 Sep 2020 12:55:24

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:55:16', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75027077-7e52-498a-9a25-987ac6512c34' User entered 'No (N)'	System	23 Sep 2020 12:55:24
	System	23 Sep 2020 12:55:24

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:55:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75027077-7e52-498a-9a25-987ac6512c34' User entered 'None (1)'	System	23 Sep 2020 12:55:24
	System	23 Sep 2020 12:55:24

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T08:55:21', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75027077-7e52-498a-9a25-987ac6512c34' User entered '23 Sep 2020 08:55'	System	23 Sep 2020 12:55:24
	System	23 Sep 2020 12:55:24

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 08:49'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 11:19'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T17:10:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e568e8f5-e2fb-448e-a462-e6213d88a22f' User entered 'None (1)'	System	23 Sep 2020 21:11:00
	System	23 Sep 2020 21:11:00

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T17:10:49', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e568e8f5-e2fb-448e-a462-e6213d88a22f' User entered 'No (N)'	System	23 Sep 2020 21:11:00
	System	23 Sep 2020 21:11:00

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T17:10:51', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e568e8f5-e2fb-448e-a462-e6213d88a22f' User entered 'No (N)'	System	23 Sep 2020 21:11:00
	System	23 Sep 2020 21:11:00

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T17:10:53', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e568e8f5-e2fb-448e-a462-e6213d88a22f' User entered 'None (1)'	System	23 Sep 2020 21:11:00
	System	23 Sep 2020 21:11:00

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-23T17:10:57', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e568e8f5-e2fb-448e-a462-e6213d88a22f' User entered '23 Sep 2020 17:10'	System	23 Sep 2020 21:11:00
	System	23 Sep 2020 21:11:00

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 2'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb074962-bb9f-4cd4-8ed3-456da02cdd8a' User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	25 Sep 2020 11:14:58
		25 Sep 2020 11:14:58

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:34', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb074962-bb9f-4cd4-8ed3-456da02cdd8a' User entered 'No (N)'	System	25 Sep 2020 11:14:58
	System	25 Sep 2020 11:14:58

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb074962-bb9f-4cd4-8ed3-456da02cdd8a' User entered 'No (N)'	System	25 Sep 2020 11:14:58
	System	25 Sep 2020 11:14:58

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:51', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb074962-bb9f-4cd4-8ed3-456da02cdd8a' User entered 'None (1)'	System	25 Sep 2020 11:14:58
	System	25 Sep 2020 11:14:58

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:14:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb074962-bb9f-4cd4-8ed3-456da02cdd8a' User entered '25 Sep 2020 07:14'	System	25 Sep 2020 11:14:58
	System	25 Sep 2020 11:14:58

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 3'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c145ea58-47d6-4d1d-9843-adb6a1c40f56' User entered 'None (1)'	System	26 Sep 2020 13:57:02
	System	26 Sep 2020 13:57:02

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c145ea58-47d6-4d1d-9843-adb6a1c40f56' User entered 'No (N)'	System	26 Sep 2020 13:57:02
	System	26 Sep 2020 13:57:02

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c145ea58-47d6-4d1d-9843-adb6a1c40f56'	System	26 Sep 2020 13:57:02
User entered 'No (N)'	System	26 Sep 2020 13:57:02

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:56:57', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c145ea58-47d6-4d1d-9843-adb6a1c40f56' User entered 'None (1)'	System	26 Sep 2020 13:57:02
	System	26 Sep 2020 13:57:02

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c145ea58-47d6-4d1d-9843-adb6a1c40f56' User entered '26 Sep 2020 09:57'	System	26 Sep 2020 13:57:02
	System	26 Sep 2020 13:57:02

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 4'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:10', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb1afd48-5b59-41b1-86bd-79dde46c248a' User entered 'None (1)'	System	27 Sep 2020 11:24:27
	System	27 Sep 2020 11:24:27

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:12', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb1afd48-5b59-41b1-86bd-79dde46c248a' User entered 'No (N)'	System	27 Sep 2020 11:24:27
	System	27 Sep 2020 11:24:27

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:20', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb1afd48-5b59-41b1-86bd-79dde46c248a' User entered 'No (N)'	System	27 Sep 2020 11:24:27
	System	27 Sep 2020 11:24:27

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:23', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb1afd48-5b59-41b1-86bd-79dde46c248a' User entered 'None (1)'	System	27 Sep 2020 11:24:27
	System	27 Sep 2020 11:24:27

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:25', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'bb1afd48-5b59-41b1-86bd-79dde46c248a' User entered '27 Sep 2020 07:24'	System	27 Sep 2020 11:24:27
	System	27 Sep 2020 11:24:27

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 5'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c78ee2a0-0205-4d60-902f-0500b4cc8386'	System	27 Sep 2020 16:01:10
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 16:01:10

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:46', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c78ee2a0-0205-4d60-902f-0500b4cc8386' User entered 'No (N)'	System	27 Sep 2020 16:01:10
	System	27 Sep 2020 16:01:10

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:49', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c78ee2a0-0205-4d60-902f-0500b4cc8386' User entered 'No (N)'	System	27 Sep 2020 16:01:10
	System	27 Sep 2020 16:01:10

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:51', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c78ee2a0-0205-4d60-902f-0500b4cc8386' User entered 'None (1)'	System	27 Sep 2020 16:01:10
	System	27 Sep 2020 16:01:10

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:00:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c78ee2a0-0205-4d60-902f-0500b4cc8386' User entered '27 Sep 2020 12:00'	System	27 Sep 2020 16:01:10
	System	27 Sep 2020 16:01:10

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 6'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:31', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '717dd413-23ec-446f-93b0-7f1a98a02266'	System	28 Sep 2020 18:25:45
User entered 'None (1)'	System	28 Sep 2020 18:25:45

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '717dd413-23ec-446f-93b0-7f1a98a02266' User entered 'No (N)'	System	28 Sep 2020 18:25:45
	System	28 Sep 2020 18:25:45

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '717dd413-23ec-446f-93b0-7f1a98a02266' User entered 'No (N)'	System	28 Sep 2020 18:25:45
	System	28 Sep 2020 18:25:45

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '717dd413-23ec-446f-93b0-7f1a98a02266'	System	28 Sep 2020 18:25:45
User entered 'None (1)'	System	28 Sep 2020 18:25:45

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:40', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '717dd413-23ec-446f-93b0-7f1a98a02266' User entered '28 Sep 2020 14:25'	System	28 Sep 2020 18:25:45
	System	28 Sep 2020 18:25:45

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 7'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:20', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8067edb7-8ae0-46a1-a2e1-51dd1ca16fae' User entered 'None (1)'	System	29 Sep 2020 16:44:37
	System	29 Sep 2020 16:44:37

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:22', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8067edb7-8ae0-46a1-a2e1-51dd1ca16fae' User entered 'No (N)'	System	29 Sep 2020 16:44:37
	System	29 Sep 2020 16:44:37

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:24', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8067edb7-8ae0-46a1-a2e1-51dd1ca16fae' User entered 'No (N)'	System	29 Sep 2020 16:44:37
	System	29 Sep 2020 16:44:37

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:25', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8067edb7-8ae0-46a1-a2e1-51dd1ca16fae' User entered 'None (1)'	System	29 Sep 2020 16:44:37
	System	29 Sep 2020 16:44:37

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8067edb7-8ae0-46a1-a2e1-51dd1ca16fae' User entered '29 Sep 2020 12:44'	System	29 Sep 2020 16:44:37
	System	29 Sep 2020 16:44:37

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 08:49'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 11:19'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:38:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered 'None (0)'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:38:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141'	System	24 Sep 2020 10:39:21
User entered 'Some interference with activity (2)'	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:01', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141'	System	24 Sep 2020 10:39:21
User entered 'Some interference with activity (2)'	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:05', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered 'Some interference with activity (2)'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:08', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered 'None (0)'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:11', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered 'None (0)'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:14', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered 'No (N)'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-24T06:39:18', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f7fe2bf0-24fc-4b23-9944-9da3b2b8d141' User entered '24 Sep 2020 06:39'	System	24 Sep 2020 10:39:21
	System	24 Sep 2020 10:39:21

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 2'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'None (0)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'Significant; prevents daily activity (3)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:22', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'Some interference with activity (2)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:26', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'Some interference with activity (2)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e'	System	25 Sep 2020 11:15:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'None (0)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered 'No (N)'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-25T07:15:40', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fba1d0bc-b0ca-499a-a910-b5e0b6caa25e' User entered '25 Sep 2020 07:15'	System	25 Sep 2020 11:15:45
	System	25 Sep 2020 11:15:45

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 3'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:04', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:08', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:09', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:11', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'None (0)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered 'No (N)'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-26T09:57:17', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '5abf19eb-4b09-4c08-a7a5-f9d3d8cdfda7' User entered '26 Sep 2020 09:57'	System	26 Sep 2020 13:57:18
	System	26 Sep 2020 13:57:18

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 4'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:31', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:39', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'None (0)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered 'No (N)'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T07:24:43', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '9c61fc34-5964-4fdf-a5bf-0798970994be' User entered '27 Sep 2020 07:24'	System	27 Sep 2020 11:24:49
	System	27 Sep 2020 11:24:49

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 5'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:01', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:03', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:04', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:08', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:10', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'None (0)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered 'No (N)'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-27T12:01:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7a7cdf4-7172-467b-adbb-d9219d9af90d' User entered '27 Sep 2020 12:01'	System	27 Sep 2020 16:01:40
	System	27 Sep 2020 16:01:40

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 6'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:46', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:48', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:55', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'None (0)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:25:59', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered 'No (N)'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-28T14:26:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd0df61b4-87c9-47ea-a5ed-59162ebfde8a' User entered '28 Sep 2020 14:26'	System	28 Sep 2020 18:26:07
	System	28 Sep 2020 18:26:07

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Sep 2020 12:34:13
User entered 'Day 7'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:34', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:39', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'None (0)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered 'No (N)'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-09-29T12:44:48', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '6a459337-b45d-4a24-bf1b-ed38e32ef901' User entered '29 Sep 2020 12:44'	System	29 Sep 2020 16:44:52
	System	29 Sep 2020 16:44:52

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:34:13

US3222299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:34:13

US3222299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	15 Oct 2020 19:36:58

US3222299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '30 Sep 2020'	Albert Garcia (b) (4)	15 Oct 2020 19:36:58

US3222299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	15 Oct 2020 19:36:58

US3222299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Albert Garcia (b) (4)	15 Oct 2020 19:36:58

US3222299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	15 Oct 2020 19:37:03

US3222299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	15 Oct 2020 19:37:03

US3222299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	15 Oct 2020 19:37:23

US3222299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '7 Oct 2020'	Albert Garcia (b) (4)	15 Oct 2020 19:37:23

US3222299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	15 Oct 2020 19:37:23

US3222299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	Albert Garcia (b) (4)	15 Oct 2020 19:37:23

US3222299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	15 Oct 2020 19:37:37

US3222299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	15 Oct 2020 19:37:37

US3222299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:19:42

US3222299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '14 Oct 2020'	Albert Garcia (b) (4)	21 Oct 2020 12:19:42

US3222299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	21 Oct 2020 12:19:42

US3222299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) Albert Garcia (b) (4)	21 Oct 2020 12:19:42

US3222299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:19:28

US3222299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	21 Oct 2020 12:19:28

US3222299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:20:58

US3222299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered '21 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:20:58

US3222299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	21 Oct 2020 12:20:58

US3222299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'VISIT3'	System	21 Oct 2020 12:20:58

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered 'No (N)'	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered empty.	System	21 Oct 2020 12:21:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04

US3222299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered 'No (N)'	Albert Garcia (b) (4)	21 Oct 2020 12:21:10

US3222299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:39:29
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:21:10

US3222299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:21:26

US3222299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '21 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:21:26

US3222299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '07:38'	Albert Garcia (b) (4)	21 Oct 2020 12:21:26

US3222299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered '21 Oct 2020 07:38'	System	21 Oct 2020 12:21:26

US3222299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:21:30

US3222299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	21 Oct 2020 12:21:30

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 64'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-10-23T06:28:33', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c40c4ef5-eb56-46fa-ad9f-41aad189b6e5' User entered 'No (N)'	System	23 Oct 2020 10:28:47
	System	23 Oct 2020 10:28:47

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-10-23T06:28:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c40c4ef5-eb56-46fa-ad9f-41aad189b6e5' User entered 'No (N)'	System	23 Oct 2020 10:28:47
	System	23 Oct 2020 10:28:47

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-10-23T06:28:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c40c4ef5-eb56-46fa-ad9f-41aad189b6e5' User entered '23 Oct 2020 06:28:42'	System	23 Oct 2020 10:28:47
	System	23 Oct 2020 10:28:47

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '23 Oct 2020 00:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '27 Oct 2020 23:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 71'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-02T17:44:41', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b96f4ec7-b073-4628-b818-cb90de2cb2ff' User entered 'No (N)'	System	02 Nov 2020 22:44:50
	System	02 Nov 2020 22:44:50

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-02T17:44:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b96f4ec7-b073-4628-b818-cb90de2cb2ff' User entered 'No (N)'	System	02 Nov 2020 22:44:50
	System	02 Nov 2020 22:44:50

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-02T17:44:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'b96f4ec7-b073-4628-b818-cb90de2cb2ff' User entered '02 Nov 2020 17:44:47'	System	02 Nov 2020 22:44:50
	System	02 Nov 2020 22:44:50

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '30 Oct 2020 00:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '03 Nov 2020 23:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 78'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-10T11:59:13', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '54b9dd73-7d6f-4630-9d88-72db82d870ae'	System	10 Nov 2020 16:59:23
User entered 'No (N)'	System	10 Nov 2020 16:59:23

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-10T11:59:15', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '54b9dd73-7d6f-4630-9d88-72db82d870ae'	System	10 Nov 2020 16:59:23
User entered 'No (N)'	System	10 Nov 2020 16:59:23

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-10T11:59:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '54b9dd73-7d6f-4630-9d88-72db82d870ae' User entered '10 Nov 2020 11:59:19'	System	10 Nov 2020 16:59:23
	System	10 Nov 2020 16:59:23

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '06 Nov 2020 00:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:08:35
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '10 Nov 2020 23:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58
Data entry locked.	System	23 Aug 2020 19:48:58
User entered 'Day 92'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Please 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)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Please 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)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Please 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)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '20 Nov 2020 00:01'	System	23 Aug 2020 19:48:58

US3222299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:58
Data entry locked.	System	23 Aug 2020 19:48:58
User entered '24 Nov 2020 23:59'	System	23 Aug 2020 19:48:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 Nov 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 Nov 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-26T12:02:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c223fa3f-01be-45df-a78d-adb66e67a49f' User entered 'No (N)'	System	26 Nov 2020 17:02:46
	System	26 Nov 2020 17:02:46

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-26T12:02:35', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c223fa3f-01be-45df-a78d-adb66e67a49f' User entered 'No (N)'	System	26 Nov 2020 17:02:46

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-11-26T12:02:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'c223fa3f-01be-45df-a78d-adb66e67a49f' User entered '26 Nov 2020 12:02:42'	System	26 Nov 2020 17:02:46
	System	26 Nov 2020 17:02:46

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 Nov 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 Nov 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-05T12:05:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75d82c55-011f-45d4-bef8-e64a0e8f47dc'	System	05 Dec 2020 17:05:58
User entered 'No (N)'	System	05 Dec 2020 17:05:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-05T12:05:53', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75d82c55-011f-45d4-bef8-e64a0e8f47dc'	System	05 Dec 2020 17:05:58
User entered 'No (N)'	System	05 Dec 2020 17:05:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-05T12:05:56', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '75d82c55-011f-45d4-bef8-e64a0e8f47dc' User entered '05 Dec 2020 12:05:56'	System	05 Dec 2020 17:05:58
	System	05 Dec 2020 17:05:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Dec 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Dec 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-08T01:18:42', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '19b8f00e-2879-4196-b3fa-f2d9f489c24e' User entered 'No (N)'	System	08 Dec 2020 06:19:05
	System	08 Dec 2020 06:19:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-08T01:18:52', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '19b8f00e-2879-4196-b3fa-f2d9f489c24e' User entered 'No (N)'	System	08 Dec 2020 06:19:05
	System	08 Dec 2020 06:19:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-08T01:18:57', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '19b8f00e-2879-4196-b3fa-f2d9f489c24e' User entered '08 Dec 2020 01:18:57'	System	08 Dec 2020 06:19:05
	System	08 Dec 2020 06:19:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Dec 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Dec 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-17T12:00:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f8c873aa-d5a5-42e6-82d3-bcb04b4ea4ad'	System	17 Dec 2020 17:00:42
User entered 'No (N)'	System	17 Dec 2020 17:00:42

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-17T12:00:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f8c873aa-d5a5-42e6-82d3-bcb04b4ea4ad'	System	17 Dec 2020 17:00:42
User entered 'No (N)'	System	17 Dec 2020 17:00:42

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-17T12:00:36', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'f8c873aa-d5a5-42e6-82d3-bcb04b4ea4ad' User entered '17 Dec 2020 12:00:36'	System	17 Dec 2020 17:00:42
	System	17 Dec 2020 17:00:42

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Dec 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Dec 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-22T04:57:45', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '700ac993-4f9e-45d3-a855-33fadb989497'	System	22 Dec 2020 09:57:57
User entered 'No (N)'	System	22 Dec 2020 09:57:57

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-22T04:57:48', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '700ac993-4f9e-45d3-a855-33fadb989497'	System	22 Dec 2020 09:57:57
User entered 'No (N)'	System	22 Dec 2020 09:57:57

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-22T04:57:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '700ac993-4f9e-45d3-a855-33fadb989497' User entered '22 Dec 2020 04:57:54'	System	22 Dec 2020 09:57:57
	System	22 Dec 2020 09:57:57

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Dec 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Dec 2020 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:06:25', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3' User entered 'Yes (Y)'	System	29 Dec 2020 05:08:15
	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:06:39', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3'	System	29 Dec 2020 05:08:15
User entered 'Yes (Y)'	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Please 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:06:46', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3'	System	29 Dec 2020 05:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:07:44', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3' User entered 'No (N)'	System	29 Dec 2020 05:08:15
	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:07:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3' User entered 'No (N)'	System	29 Dec 2020 05:08:15
	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2020-12-29T00:08:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '99ac186e-168c-431e-9c3f-0bb6b07af9a3' User entered '29 Dec 2020 00:08:06'	System	29 Dec 2020 05:08:15
	System	29 Dec 2020 05:08:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 Dec 2020 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Jan 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-07T12:03:46', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2aa10cb0-d52e-4539-90b2-3ebf9effecb6'	System	07 Jan 2021 17:03:53
User entered 'No (N)'	System	07 Jan 2021 17:03:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-07T12:03:48', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2aa10cb0-d52e-4539-90b2-3ebf9effecb6'	System	07 Jan 2021 17:03:53
User entered 'No (N)'	System	07 Jan 2021 17:03:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-07T12:03:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2aa10cb0-d52e-4539-90b2-3ebf9effecb6' User entered '07 Jan 2021 12:03:50'	System	07 Jan 2021 17:03:53
	System	07 Jan 2021 17:03:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Jan 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Jan 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-14T09:39:54', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4d2fd65e-ab1d-4ebc-b9bc-f814d36dd8fa' User entered 'No (N)'	System	14 Jan 2021 14:40:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-14T09:39:58', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4d2fd65e-ab1d-4ebc-b9bc-f814d36dd8fa' User entered 'No (N)'	System	14 Jan 2021 14:40:05
	System	14 Jan 2021 14:40:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-14T09:40:02', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4d2fd65e-ab1d-4ebc-b9bc-f814d36dd8fa' User entered '14 Jan 2021 09:40:02'	System	14 Jan 2021 14:40:05
	System	14 Jan 2021 14:40:05

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Jan 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Jan 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-21T12:00:32', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '917fb63a-87b0-47da-984e-bf32b59ce587'	System	21 Jan 2021 17:00:55
User entered 'No (N)'	System	21 Jan 2021 17:00:55

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-21T12:00:34', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '917fb63a-87b0-47da-984e-bf32b59ce587' User entered 'No (N)'	System	21 Jan 2021 17:00:55
	System	21 Jan 2021 17:00:55

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-21T12:00:38', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '917fb63a-87b0-47da-984e-bf32b59ce587' User entered '21 Jan 2021 12:00:38'	System	21 Jan 2021 17:00:55
	System	21 Jan 2021 17:00:55

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Jan 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Jan 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-26T13:42:47', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1c67e9ea-d7e5-4a35-a62e-71be86a30422' User entered 'No (N)'	System	26 Jan 2021 19:49:28
	System	26 Jan 2021 19:49:28

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-26T13:42:50', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1c67e9ea-d7e5-4a35-a62e-71be86a30422' User entered 'No (N)'	System	26 Jan 2021 19:49:28
	System	26 Jan 2021 19:49:28

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-01-26T13:42:53', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '1c67e9ea-d7e5-4a35-a62e-71be86a30422' User entered '26 Jan 2021 13:42:53'	System	26 Jan 2021 19:49:28
	System	26 Jan 2021 19:49:28

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Jan 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Jan 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-02T05:47:04', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8c8ade59-63a6-4b0f-b990-79c174a51e7e' User entered 'No (N)'	System	02 Feb 2021 10:47:15
	System	02 Feb 2021 10:47:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-02T05:47:06', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8c8ade59-63a6-4b0f-b990-79c174a51e7e' User entered 'No (N)'	System	02 Feb 2021 10:47:15
	System	02 Feb 2021 10:47:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-02T05:47:09', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '8c8ade59-63a6-4b0f-b990-79c174a51e7e' User entered '02 Feb 2021 05:47:09'	System	02 Feb 2021 10:47:15
	System	02 Feb 2021 10:47:15

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Feb 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Feb 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-12T17:53:29', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2698d956-66a1-4ab3-befa-56764b71ec11' User entered 'No (N)'	System	12 Feb 2021 22:53:40
	System	12 Feb 2021 22:53:40

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-12T17:53:34', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2698d956-66a1-4ab3-befa-56764b71ec11'	System	12 Feb 2021 22:53:40
User entered 'No (N)'	System	12 Feb 2021 22:53:40

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-12T17:53:37', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '2698d956-66a1-4ab3-befa-56764b71ec11' User entered '12 Feb 2021 17:53:37'	System	12 Feb 2021 22:53:40
	System	12 Feb 2021 22:53:40

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Feb 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Feb 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-19T17:59:16', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7a680613-0b73-4dcd-8804-10229016c41f' User entered 'No (N)'	System	19 Feb 2021 22:59:24
	System	19 Feb 2021 22:59:24

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-19T17:59:19', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7a680613-0b73-4dcd-8804-10229016c41f' User entered 'No (N)'	System	19 Feb 2021 22:59:24
	System	19 Feb 2021 22:59:24

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-19T17:59:22', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '7a680613-0b73-4dcd-8804-10229016c41f' User entered '19 Feb 2021 17:59:22'	System	19 Feb 2021 22:59:24
	System	19 Feb 2021 22:59:24

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Feb 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Feb 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-25T12:00:19-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd99252a7-06c8-4c9d-acfa-3fd531588dcd' User entered 'No (N)'	System	25 Feb 2021 17:00:51
	System	25 Feb 2021 17:00:51

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-25T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd99252a7-06c8-4c9d-acfa-3fd531588dcd' User entered 'No (N)'	System	25 Feb 2021 17:00:51
	System	25 Feb 2021 17:00:51

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-02-25T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'd99252a7-06c8-4c9d-acfa-3fd531588dcd' User entered '25 Feb 2021 17:00:26'	System	25 Feb 2021 17:00:51
	System	25 Feb 2021 17:00:51

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Feb 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Feb 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-04T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '40f860fb-e0ec-41b3-90c5-0637455ec3c0'	System	04 Mar 2021 17:02:50
User entered 'No (N)'	System	04 Mar 2021 17:02:50

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-04T12:00:53-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '40f860fb-e0ec-41b3-90c5-0637455ec3c0'	System	04 Mar 2021 17:02:50
User entered 'No (N)'	System	04 Mar 2021 17:02:50

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-04T12:01:00-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '40f860fb-e0ec-41b3-90c5-0637455ec3c0'	System	04 Mar 2021 17:02:50
User entered '04 Mar 2021 12:01:00'	System	04 Mar 2021 17:02:50

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Mar 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Mar 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-11T12:00:19-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fac2be66-b6df-495f-80a4-f873f8174e8b'	System	11 Mar 2021 17:00:38
User entered 'No (N)'	System	11 Mar 2021 17:00:38

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-11T12:00:24-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fac2be66-b6df-495f-80a4-f873f8174e8b'	System	11 Mar 2021 17:00:38
User entered 'No (N)'	System	11 Mar 2021 17:00:38

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-11T12:00:28-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'fac2be66-b6df-495f-80a4-f873f8174e8b' User entered '11 Mar 2021 12:00:28'	System	11 Mar 2021 17:00:38
	System	11 Mar 2021 17:00:38

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Mar 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Mar 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-19T18:52:04-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '63a31350-8958-43b3-ad71-77bf3ff2625d'	System	19 Mar 2021 22:52:12
User entered 'No (N)'	System	19 Mar 2021 22:52:12

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-19T18:52:06-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '63a31350-8958-43b3-ad71-77bf3ff2625d'	System	19 Mar 2021 22:52:12
User entered 'No (N)'	System	19 Mar 2021 22:52:12

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-19T18:52:09-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '63a31350-8958-43b3-ad71-77bf3ff2625d' User entered '19 Mar 2021 18:52:09'	System	19 Mar 2021 22:52:12
	System	19 Mar 2021 22:52:12

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Mar 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Mar 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-25T12:00:28-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7b1d2bf-f791-4316-b801-62d8724e3357'	System	25 Mar 2021 16:01:20
User entered 'No (N)'	System	25 Mar 2021 16:01:20

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-25T12:00:30-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7b1d2bf-f791-4316-b801-62d8724e3357'	System	25 Mar 2021 16:01:20
User entered 'No (N)'	System	25 Mar 2021 16:01:20

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-25T12:00:34-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'e7b1d2bf-f791-4316-b801-62d8724e3357' User entered '25 Mar 2021 12:00:34'	System	25 Mar 2021 16:01:20
	System	25 Mar 2021 16:01:20

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Mar 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Mar 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-01T12:00:20-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'dac7577c-f8a3-402d-afb5-4b1f7a4c940f'	System	01 Apr 2021 16:00:47
User entered 'No (N)'	System	01 Apr 2021 16:00:47

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-01T12:00:24-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'dac7577c-f8a3-402d-afb5-4b1f7a4c940f' User entered 'No (N)'	System	01 Apr 2021 16:00:47
	System	01 Apr 2021 16:00:47

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-01T12:00:27-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'dac7577c-f8a3-402d-afb5-4b1f7a4c940f'	System	01 Apr 2021 16:00:47
User entered '01 Apr 2021 12:00:27'	System	01 Apr 2021 16:00:47

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Mar 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '03 Apr 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-08T12:00:20-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '84c77523-903b-4a93-bd8b-7ee90b826100'	System	08 Apr 2021 16:19:32
User entered 'No (N)'	System	08 Apr 2021 16:19:32

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-08T12:19:05-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '84c77523-903b-4a93-bd8b-7ee90b826100'	System	08 Apr 2021 16:19:32
User entered 'No (N)'	System	08 Apr 2021 16:19:32

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-08T12:19:09-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '84c77523-903b-4a93-bd8b-7ee90b826100'	System	08 Apr 2021 16:19:32
User entered '08 Apr 2021 12:19:09'	System	08 Apr 2021 16:19:32

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Apr 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '10 Apr 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-15T12:00:31-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4182d982-d542-4906-83ec-9e0906268de4'	System	15 Apr 2021 16:00:53
User entered 'No (N)'	System	15 Apr 2021 16:00:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-15T12:00:33-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4182d982-d542-4906-83ec-9e0906268de4'	System	15 Apr 2021 16:00:53
User entered 'No (N)'	System	15 Apr 2021 16:00:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-15T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4182d982-d542-4906-83ec-9e0906268de4'	System	15 Apr 2021 16:00:53
User entered '15 Apr 2021 12:00:36'	System	15 Apr 2021 16:00:53

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Apr 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 Apr 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-21T09:21:06-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4900e581-4912-4363-b55e-77f1e0f78087'	System	21 Apr 2021 13:21:16
User entered 'No (N)'	System	21 Apr 2021 13:21:16

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-21T09:21:08-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4900e581-4912-4363-b55e-77f1e0f78087'	System	21 Apr 2021 13:21:16
User entered 'No (N)'	System	21 Apr 2021 13:21:16

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-21T09:21:11-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '4900e581-4912-4363-b55e-77f1e0f78087'	System	21 Apr 2021 13:21:16
User entered '21 Apr 2021 09:21:11'	System	21 Apr 2021 13:21:16

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Apr 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 Apr 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-29T12:00:22-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'effa4a2c-a0a3-4929-bc9c-df8fc6b8e9db' User entered 'No (N)'	System	29 Apr 2021 16:00:44
	System	29 Apr 2021 16:00:44

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

Have you been exposed to someone with 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 (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-29T12:00:23-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'effa4a2c-a0a3-4929-bc9c-df8fc6b8e9db' User entered 'No (N)'	System	29 Apr 2021 16:00:44
	System	29 Apr 2021 16:00:44

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-04-29T12:00:26-04:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: 'effa4a2c-a0a3-4929-bc9c-df8fc6b8e9db'	System	29 Apr 2021 16:00:44
User entered '29 Apr 2021 12:00:26'	System	29 Apr 2021 16:00:44

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Apr 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 May 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 May 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 May 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 May 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 May 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 May 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 May 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 May 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 May 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Jun 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Jun 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Jun 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Jun 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Jun 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Jun 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Jun 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Jun 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 Jun 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '03 Jul 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Jul 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '10 Jul 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Jul 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 Jul 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Jul 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 Jul 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Jul 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '31 Jul 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '03 Aug 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '07 Aug 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '10 Aug 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '14 Aug 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 Aug 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 Aug 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 Aug 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 Aug 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '31 Aug 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 Sep 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '07 Sep 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 Sep 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '14 Sep 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 Sep 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 Sep 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 Sep 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 Sep 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Oct 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Oct 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Oct 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Oct 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Oct 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Oct 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Oct 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Oct 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Oct 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Nov 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Nov 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Nov 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Nov 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Nov 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Nov 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Nov 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Nov 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Nov 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 Dec 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '07 Dec 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 Dec 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '14 Dec 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 Dec 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 Dec 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 Dec 2021 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 Dec 2021 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Jan 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 Jan 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Jan 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 Jan 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Jan 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 Jan 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Jan 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 Jan 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 Jan 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Feb 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Feb 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Feb 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Feb 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Feb 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Feb 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Feb 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Feb 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Mar 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Mar 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Mar 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Mar 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Mar 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Mar 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Mar 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Mar 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 Mar 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Apr 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Apr 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Apr 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Apr 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Apr 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Apr 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Apr 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Apr 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Apr 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '03 May 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '07 May 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '10 May 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '14 May 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 May 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 May 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 May 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 May 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '31 May 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 Jun 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '07 Jun 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 Jun 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '14 Jun 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 Jun 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '21 Jun 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 Jun 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '28 Jun 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Jul 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '05 Jul 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Jul 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '12 Jul 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Jul 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '19 Jul 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Jul 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '26 Jul 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Jul 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '02 Aug 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Aug 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '09 Aug 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Aug 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '16 Aug 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Aug 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '23 Aug 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Aug 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '30 Aug 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '03 Sep 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '06 Sep 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '10 Sep 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '13 Sep 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '17 Sep 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '20 Sep 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '24 Sep 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '27 Sep 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '01 Oct 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '04 Oct 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '08 Oct 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '11 Oct 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '15 Oct 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '18 Oct 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '22 Oct 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '25 Oct 2022 00:01'	System	20 Nov 2020 01:28:58

US3222299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:58
Amendment Manager: User entered '29 Oct 2022 23:59'	System	20 Nov 2020 01:28:58

US3222299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:06:41

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)	25 Apr 2021 06:32:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-04T12:01:04-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '50352114-44fe-4aac-b097-2341a33aa325'	System	04 Mar 2021 17:03:14
User entered 'No (N)'	System	04 Mar 2021 17:03:14

US3222299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:06:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE01D4F1-69F5-4279-A938-717AA2C5C689)', Time: '2021-03-04T12:01:08-05:00', User OID: 'PatientReportedOutcome (US3222299)', ODM File OID: '50352114-44fe-4aac-b097-2341a33aa325' User entered '04 Mar 2021 12:01:08'	System	04 Mar 2021 17:03:14
	System	04 Mar 2021 17:03:14

US3222299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:52:06

US3222299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:52:06

US3222299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:52:06

US3222299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:52:06

US3222299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:02:41

US3222299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:37:04
User entered 'I'	System	18 Jan 2021 16:02:41

US3222299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:03:06

US3222299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:03:06

US3222299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:03:06

US3222299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:03:06

US3222299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:03:09

US3222299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User entered 'I'	System	18 Jan 2021 16:03:09

US3222299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:05:55

US3222299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:05:55

US3222299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:05:55

US3222299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:05:55

US3222299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:05:59

US3222299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User entered 'I'	System	18 Jan 2021 16:05:59

US3222299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:56:01

US3222299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:56:01

US3222299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:56:01

US3222299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:56:01

US3222299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:56:06

US3222299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:32:36
User entered 'I'	System	18 Feb 2021 14:56:06

US3222299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:15:19
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered '31 Mar 2021'	douglas winter (b) (4)	02 Apr 2021 16:15:19
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered 'Clinic (Clinic)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Apr 2021 16:15:19

US3222299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	02 Apr 2021 16:15:19

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:15:24

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:15:24

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:15:24

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:15:24

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:24
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:15:24

US3222299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	02 Apr 2021 16:15:29
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:15:29
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:15:47
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered '31 Mar 2021'	douglas winter (b) (4)	02 Apr 2021 16:15:47
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered '14:25'	douglas winter (b) (4)	02 Apr 2021 16:15:47
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 14:25'	System	02 Apr 2021 16:15:47

US3222299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:15:52
	(b) (4)	

US3222299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 16:15:52

US3222299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:56:28

US3222299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:56:28

US3222299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:56:28

US3222299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:56:28

US3222299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:06:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:56:31

US3222299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:56:31

US3222299

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

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:12:12
	(b) (4)	

US3222299

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

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '31 Mar 2021'	douglas winter (b) (4)	02 Apr 2021 16:12:12
	(b) (4)	

US3222299

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

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Clinic (Clinic)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Apr 2021 16:12:12

US3222299

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

Form: Visit Date

Generated On: 09 Jun 2021 16:06:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	02 Apr 2021 16:12:12

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per CDM RQ: Per response "updated" however the update is not obvious. Please consider to update either Date of updated Informed consent or check the NA box, as both the fields can not be blank. thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:12:46
Query 'Per CDM RQ: Per response "updated" however the update is not obvious. Please consider to update either Date of updated Informed consent or check the NA box, as both the fields can not be blank. thank you' answered with 'corrected per source' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:41:25
User entered '31 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 12:40:22
User opened query 'Per CDM RQ: Per response "updated" however the update is not obvious. Please consider to update either Date of updated Informed consent or check the NA box, as both the fields can not be blank. thank you' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:15
User closed query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:15
Query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'updated' (Site from DM).	Jennifer Dittman (b) (4) (b) (4)	08 Apr 2021 19:52:19

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:34:53
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	02 Apr 2021 16:12:39
User entered '31 Mar 2021' reason for change: Data Entry Error	douglas winter (b) (4)	02 Apr 2021 16:12:21
User entered empty.	douglas winter (b) (4)	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	02 Apr 2021 16:11:58
	(b) (4)	

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:11:58
	(b) (4)	

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4)	
Query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:41
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	08 Apr 2021 19:52:26
User opened query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4)	
User entered 'Amendment 5 (Amendment 5)'	Jennifer Dittman (b) (4)	08 Apr 2021 19:51:40
	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 10:39:11
	douglas winter (b) (4)	02 Apr 2021 16:11:58
	(b) (4)	

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:12:57
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'patient was unblinded on the phone prior to appointment' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 12:40:55
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	09 Apr 2021 12:40:22
User closed query 'Per CDM: Per IRT, subject was unblinded on 05JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:43
Query 'Per CDM: Per IRT, subject was unblinded on 05JAN2021. Please review and reconcile.' answered with 'updated' (Site from DM).	Jennifer Dittman (b) (4) (b) (4)	08 Apr 2021 19:52:31
User entered '5 Jan 2021' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	08 Apr 2021 19:52:05
User opened query 'Per CDM: Per IRT, subject was unblinded on 05JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:57:37
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	02 Apr 2021 16:12:39
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	02 Apr 2021 16:12:39
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	02 Apr 2021 16:12:21
User entered '6 Jan 2021'	douglas winter (b) (4) (b) (4)	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	02 Apr 2021 16:11:58
	(b) (4)	

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:11:58

US3222299

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

Form: Unblinding

Generated On: 09 Jun 2021 16:06:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:11:58

US3222299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:12:55
	(b) (4)	

US3222299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '31 Mar 2021'	douglas winter (b) (4)	02 Apr 2021 16:12:55
	(b) (4)	

US3222299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '14:25'	douglas winter (b) (4)	02 Apr 2021 16:12:55
	(b) (4)	

US3222299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 14:25'	System	02 Apr 2021 16:12:55

US3222299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	02 Apr 2021 16:13:09
	(b) (4)	

US3222299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '31 Mar 2021'	douglas winter (b) (4)	02 Apr 2021 16:13:09
	(b) (4)	

US3222299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered '14:27'	douglas winter (b) (4)	02 Apr 2021 16:13:09
	(b) (4)	

US3222299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 14:27'	System	02 Apr 2021 16:13:09

US3222299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:06:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:11
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Injection site pain persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:25:23
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Injection site pain persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'symptoms recorded in AE eCRF. Source documents completed for AE' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:28:26
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Injection site pain persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 10:04:02
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:09:02
User entered 'Yes (Y)'	douglas winter (b) (4)	09 Oct 2020 14:59:24

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:09:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:56:03
User entered		
'USA-US104-2020-mRNA-1273-P301000010'	System	12 Oct 2020 12:55:58
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 12:55:58

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:09:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:12:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:12:23
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 15:11:13
User entered 'SMALL BOWEL OBSTRUCTION'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:09
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:30:19
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'Updated' (Site from DM).	douglas winter (b) (4) (b) (4)	04 Nov 2020 14:50:24
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:31:54
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:14:08
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:14
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:17
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:18
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:21
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:23
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:26
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	03 Nov 2020 21:37:24
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4)	03 Nov 2020 21:37:24
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:12:28
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	09 Oct 2020 15:11:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 15:11:10
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:16:48
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:16:50
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:37:12
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Oct 2020 15:11:34
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Oct 2020 15:11:34
User entered '1' reason for change: Data Entry Error douglas winter	(b) (4)	09 Oct 2020 15:11:34
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Oct 2020 15:11:10
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:15
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:16
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:47
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:50
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:52
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:55
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:37:57
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:16:58
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:17:03
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:26
Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	douglas winter (b) (4) (b) (4)	21 Oct 2020 17:04:30
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	21 Oct 2020 13:38:12
User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:05:59
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:19:04
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:11:10
	(b) (4)	

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:03:43
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' answered with 'con med indication updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:47:51
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:43:41
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:43:41
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated' (Site from DM).	douglas winter (b) (4) (b) (4)	04 Nov 2020 16:06:27
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:14:15
User entered '1'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:01:45
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as applicable. Otherwise, clarify.' answered with 'con procedure updated line 2' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:36:09
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:37:12
User entered '1' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 12:48:59
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:37:03
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: SAE Narrative = 03/OCT/2020 POST OPERATIVE XRAY. 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) (4), (b) (6)	08 Dec 2020 13:07:47
User closed query 'Per DM CLR: SAE Narrative = CT OF THE ABDOMEN AND PELVIS. 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)	08 Dec 2020 13:04:25
Query 'Per DM CLR: SAE Narrative = 03/OCT/2020 POST OPERATIVE XRAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to con med procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:48:26
Query 'Per DM CLR: SAE Narrative = CT OF THE ABDOMEN AND PELVIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:48:09
User opened query 'Per DM CLR: SAE Narrative = 03/OCT/2020 POST OPERATIVE XRAY. 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)	23 Nov 2020 00:44:53
User opened query 'Per DM CLR: SAE Narrative = CT OF THE ABDOMEN AND PELVIS. 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)	23 Nov 2020 00:44:26
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:27:56

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'NOT DONE' (Site from Safety). DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	04 Nov 2020 17:29:15
	douglas winter (b) (4) (b) (4)	04 Nov 2020 17:26:05
User entered 'DURING SUBJECTS DAY 43 SAFETY CALL @ 11:23 07/OCT/2020 I FOUND OUT SHE WENT INTO THE HOSPITAL ON 03/OCT/2020 FOR STOMACH DISCOMFORT. SAME DAY OF ADMISSION SHE WAS DIAGNOSED WITH HAVING A SMALL BOWEL OBSTRUCTION AFTER HAVING A CT OF THE ABDOMEN AND PELVIS SHOWED A SMALL BOWEL OBSTRUCTION AT THE MID ILEUM WHERE LOOK OF SMALL BOWEL WAS FOUND TO BE HERNIATED THROUGH OMENTUM. POST OPERATIVE. XRAY ABDOMEN VERIFIED CT RESULTS. 03/OCT/2020 POST OPERATIVE XRAY SHOWED NONOBSTRUCTIVE BOWEL GAS PATTERNS.' reason for change: Data Entry Error DataPoint Verified.	douglas winter (b) (4) (b) (4)	04 Nov 2020 17:26:05
	(b) (4), (b) (6)	03 Nov 2020 18:37:05
Query 'PV Query: Per paper SAE form, Osteoarthritis is listed as relevant medical history. Please add this MH to eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 23:41:14
User closed query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 15:16:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 15:16:08

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'PATIENTS MEDICATION ORDERS INCLUDE 150 CC OF GASTROGRAFIN, MAGNESIUM OXIDE 400 MG, SHE WAS TAKEN TO THE OR WHERE SHE RECEIVED AN NG TUBE, NP, IV FLUIDS, EMPIRIC IV ANTIBIOTICS, AND UNDERWENT EXPLORATORY LAPAROTOMY RELEASE OF CLOSED-LOOP SMALL-BOWEL OBSTRUCTION AND THEN APPLICATION OF NEGATIVE PRESSURE PICO WOUND DRESSING. ' (Site from Safety).	douglas winter (b) (4)	21 Oct 2020 17:29:36
User entered 'DURING SUBJECTS DAY 43 SAFETY CALL @ 11:23 07/OCT/2020 I FOUND OUT SHE WENT INTO THE HOSPITAL ON 03/OCT/2020 FOR STOMACH DISCOMFORT. SHE WAS DIAGNOSED WITH HAVING A SMALL BOWEL OBSTRUCTION.' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 17:15:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'DISCHARGE SUMMARY STATES THE FOLLOWING: PERTINENT LAB DATA WBC 7.2, CO2 23, LIPASE 19. LIVER FUNCTION TEST WITHIN NORMAL LIMITS, URINALYSIS ONLY PYURIA. CT SCAN OF THE ABDOMEN AND PELVIS WITH CONTRAST SHOWED AN ABNORMAL SHORT SEGMENT LOOP OF MID SMALL BOWEL WITH MORPHOLOGIC FEATURES OF A VOLVULUS OF POSSIBLY INTERNAL HERNIATIO RESULTING IN A MILD EARLY CLOSED LOOP OBSTRUCTION.' (Site from Safety).	douglas winter (b) (4)	21 Oct 2020 17:11:04
User opened query 'PV Query: Per paper SAE form, Osteoarthritis is listed as relevant medical history. Please add this MH to eCRF.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:06:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

1687 of 2054

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:05:48
User opened query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:05:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:05:29
User entered 'DURING SUBJECTS DAY 43 SAFETY CALL @ 11:23 07/OCT/2020 I FOUND OUT SHE WENT INTO THE HOSPITAL on 03/OCT/2020 FOR STOMACH DISCOMFORT. SHE WAS DIAGNOSED WITH HAVING A SMALL BOWEL OBSTRUCTION.	douglas winter (b) (4)	09 Oct 2020 15:11:10

REQUESTING MEDICAL RECORDS'

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 15:11:10

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:27:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:27:39
Data point term sent to Coder	System	20 Apr 2021 20:27:17
User entered 'injection site pain'	(b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '23 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 20:27:15
User entered '19:29' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:27:15
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 20:27:02
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User entered '23 Aug 2020 19:29'	System	20 Apr 2021 20:27:15
User entered empty.	System	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 20:27:15
User entered '16:33' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:27:15
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 20:27:02
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User entered '31 Aug 2020 16:33'	System	20 Apr 2021 20:27:15
User entered empty.	System	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User entered '0'	System	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26
User entered '0'	System	20 Apr 2021 20:27:02

US3222299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:38:26

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:11
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:20:00
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated. in conmed. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:54:26
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:31:00
User closed query 'Per ETRTR: According to SAE "Small Bowel Obstruction" CRF, medication was dosed. Please update ConMeds CRF accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:38:14
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:38:10
Query 'Per ETRTR: According to SAE "Small Bowel Obstruction" CRF, medication was dosed. Please update ConMeds CRF accordingly, thanks.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:05

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: According to SAE "Small Bowel Obstruction" CRF, medication was dosed. Please update ConMeds CRF accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Oct 2020 22:59:05
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 17:47:08

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
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)	18 Dec 2020 16:03:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 16:03:42
Data point term sent to Coder	System	18 Dec 2020 16:02:43
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 16:01:53
User closed query 'Medications from hospitalization to be added to the Con Med Log.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:05:59
Query 'Medications from hospitalization to be added to the Con Med Log.' answered with 'Updated' (Site from CRA).	douglas winter (b) (4)	04 Nov 2020 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:39:52
User opened query 'Medications from hospitalization to be added to the Con Med Log.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:39:50
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)	21 Oct 2020 12:18:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 12:18:28
Data point term sent to Coder	System	21 Oct 2020 12:17:36
User entered 'ACETAMINOPHEN'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
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 BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 09:59:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria.' answered with 'this is a solicited adverse reaction and does not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:29:33
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 BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:07:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

1732 of 2054

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
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 MILD FEVER 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 MILD FEVER did not meet the AE reporting criteria. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 08:44:30
	(b) (4), (b) (6)	18 Dec 2020 16:01:53
User entered 'BODY ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:01:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MILD FEVER 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 MILD FEVER did not meet the AE reporting criteria. ' answered with 'DOES NOT MEET REPORTING CRITERIA' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Dec 2020 18:12:06

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
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 MILD FEVER 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 MILD FEVER did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 02:55:56
	(b) (4), (b) (6)	03 Nov 2020 18:40:11
User entered 'MILD FEVER'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:40:13
User entered '500'	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:40:28
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:40:29
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Mar 2021 13:31:35
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	22 Mar 2021 13:31:35
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 13:31:35
	(b) (4), (b) (6)	
User entered 'as needed (PRN)' reason for change: Data Entry Error		22 Mar 2021 13:31:35
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Mar 2021 13:31:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:40:16
User entered 'once (ONCE)'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:40:31
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of BODY ACHES which started 24 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:01:11
Query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of BODY ACHES which started 24 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.'	(b) (4), (b) (6)	22 Mar 2021 13:31:50
answered with 'updated per e diary' (Site from DM).		
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:31:04
User opened query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of BODY ACHES which started 24 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	18 Dec 2020 16:01:53
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:01:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:40:35
User entered '24 Sep 2020'	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 18:43:27
User entered '0'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:40:43
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Un-verified.	(b) (4)	18 Dec 2020 16:01:53
	(b) (4), (b) (6)	18 Dec 2020 16:01:53
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:01:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:40:40
User entered '24 Sep 2020'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 12:16:52
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:16:52

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:54:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:54:31
Data point term sent to Coder	System	03 Nov 2020 21:53:38
User entered 'ACETAMINOPHEN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:52:41
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:03:28
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'this is a solicited adverse reaction and does not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:32:33
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 02:56:29
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:07:11
User entered 'GENERAL PAIN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:16
User entered '650'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:19
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:21
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:52:41
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:28
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:52:41
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:40
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:43
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:47
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:49
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:07:51
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:52:41
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User entered empty.	System	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User entered empty.	System	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:31
User entered empty.	System	03 Nov 2020 21:52:41

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:50:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:50:17
Data point term sent to Coder	System	03 Nov 2020 21:54:39
User entered 'ACETAMINOPHEN-OXYCODONE'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:53:59
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:03:37
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'given for pain per hospital DC summary of small bowel obstruction documented in AE' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:47:48
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 02:56:45
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:08:07
User entered 'GENERAL PAIN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:09
User entered '325'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:12
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:14
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:53:59
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:18
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:53:59
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:23
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:25
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:31
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:34
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:08:36
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:53:59
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User entered empty.	System	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User entered empty.	System	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:35
User entered empty.	System	03 Nov 2020 21:53:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:43:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:11:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 04:59:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 04:59:17
Data point term sent to Coder	System	03 Nov 2020 21:56:43
User entered 'D5 1/S NORMAL SALINE'	douglas winter (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:56:10
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:18
User entered 'SUPPLEMENT'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:21
User entered '1000'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:23
User entered 'mL (mL)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:25
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'once (ONCE)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:56:10
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:28
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:41
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:44
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:46
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:48
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:11:49
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:56:10
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User entered empty.	System	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User entered empty.	System	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:39
User entered empty.	System	03 Nov 2020 21:56:10

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:09:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:09:54
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4)	02 Dec 2020 12:36:36 02 Dec 2020 12:35:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:11:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:03:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:03:17
Data point term sent to Coder User entered 'FAMOTIDINE'	System douglas winter (b) (4)	03 Nov 2020 21:57:49 03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:57:38
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 09:58:29
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'SBO documented in AE per hospital dc summary' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:48:45
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:03:25
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 02:58:35
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 02:58:16
DataPoint Un-verified.	gail lavine (b) (4)	02 Dec 2020 12:35:54
User entered 'abdominal pain secondary to small bowel obstruction' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	02 Dec 2020 12:35:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:11:59

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'H2 BLOCKER'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:02
User entered '20'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:05
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'EVERY 12 HOURS'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:21
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:23
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Nov 2020 21:57:45
User entered '3 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:45
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Nov 2020 21:57:38
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:25
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:27
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:28
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User entered empty.	System	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User entered empty.	System	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:42
User entered empty.	System	03 Nov 2020 21:57:38

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:20
Data point term sent to Coder	System	03 Nov 2020 21:59:53
User entered 'MORPHINE'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:59:12
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:16:23
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	22 Mar 2021 13:49:59
' answered with 'Given for SBO per hospital Dc records. documented in AE' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 02:59:24
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:12:44
User entered 'GENERAL PAIN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:47
User entered 'l'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:50
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:12:52
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'EVERY 4 HOURS, PRN'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:59:12
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:00
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:02
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:04
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:06
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:08
User entered '4 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	04 Nov 2020 14:16:28
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 21:59:12
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User entered empty.	System	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User entered empty.	System	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:46
User entered empty.	System	03 Nov 2020 21:59:12

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:21:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:21:27
Data point term sent to Coder	System	03 Nov 2020 22:00:55
User entered 'ONDANSETRON'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:00:32
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:04:17
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4), (b) (6)	22 Mar 2021 13:50:30
' answered with 'Given for SBO per hospital Dc records. documented in AE' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4), (b) (6)	16 Dec 2020 02:59:38
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:13:17
User entered 'NAUSEA'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:20
User entered '4'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:21
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:23
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'EVERY 4 HOURS, PRN'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:00:32
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:31
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:33
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:35
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:36
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:13:39
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:00:32
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User entered empty.	System	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User entered empty.	System	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:49
User entered empty.	System	03 Nov 2020 22:00:32

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:59:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:59:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 06:05:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 06:05:28
Data point term sent to Coder	System	08 Apr 2021 20:10:17
Coding entries removed.	Crystal Paccione (b) (4)	08 Apr 2021 20:09:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:14:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:27:18

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'SALINE FLUSH'	Coder Import (b) (4) (b) (4) System douglas winter (b) (4) (b) (4)	04 Nov 2020 05:27:18 03 Nov 2020 22:02:59 03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Crystal Paccione (b) (4)	08 Apr 2021 20:09:21
User entered 'No (N)'	(b) (4)	
	douglas winter (b) (4)	03 Nov 2020 22:02:31
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:00:42
Query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' answered with 'updated' (Site from DM).	Crystal Paccione (b) (4)	08 Apr 2021 20:09:29
DataPoint Un-verified.	Crystal Paccione (b) (4)	08 Apr 2021 20:09:21
User entered 'DVT prophylaxis' reason for change:	Crystal Paccione (b) (4)	08 Apr 2021 20:09:21
Data Entry Error	(b) (4)	
User opened query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:19:46
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	25 Mar 2021 09:19:46
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	22 Mar 2021 13:50:53
' answered with 'Given for SBO per hospital Dc records. documented in AE' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	16 Dec 2020 02:59:50
' (Site from DM).		

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:14:45
User entered 'KEEP VEIN OPEN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:14:49
User entered '10'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:14:51
User entered 'mL (mL)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:14:54
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'EVERY 12 HOURS'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:18:25
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:18:28
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:18:32
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:18:35
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:18:36
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User entered empty.	System	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User entered empty.	System	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:52
User entered empty.	System	03 Nov 2020 22:02:31

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:59:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:59:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 06:05:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 06:05:30
Data point term sent to Coder	System	08 Apr 2021 20:10:17
Coding entries removed.	Crystal Paccione (b) (4)	08 Apr 2021 20:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:18:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:27:18

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Nov 2020 05:27:18
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Nov 2020 22:04:01
User entered 'SALINE FLUSH'	douglas winter (b) (4)	03 Nov 2020 22:03:35
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 20:10:09
User entered 'No (N)'	douglas winter (b) (4)	03 Nov 2020 22:03:35
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:58:33
Query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' answered with 'updated ' (Site from DM).	Crystal Paccione (b) (4)	08 Apr 2021 20:10:16
DataPoint Un-verified.	Crystal Paccione (b) (4)	08 Apr 2021 20:10:09
User entered 'DVT prophylaxis' reason for change:	Crystal Paccione (b) (4)	08 Apr 2021 20:10:09
Data Entry Error	(b) (4)	
User opened query 'Per CDM: Response noted - please consider to update current indication as per your response to previous query 'Given for SBO' else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:19:36
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	25 Mar 2021 09:19:36
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	22 Mar 2021 13:51:14
' answered with 'Given for SBO per hospital Dc records. documented in AE' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	16 Dec 2020 03:00:02
' (Site from DM).		

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:19:01
User entered 'KEEP VEIN OPEN'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:03
User entered '10'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:05
User entered 'mL (mL)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:06
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'PRN'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:03:35
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:11
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:14
User entered '3 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:18
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:19:22
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User entered empty.	System	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User entered empty.	System	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:56
User entered empty.	System	03 Nov 2020 22:03:35

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:39:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:39:38
Data point term sent to Coder DataPoint Un-verified.	System	08 Apr 2021 20:13:23
	Crystal Paccione (b) (4)	08 Apr 2021 20:13:11
Coding entries removed.	(b) (4)	
	Crystal Paccione (b) (4)	08 Apr 2021 20:13:11
User entered 'ZOSYN (Piperacillin-tazobactam)' reason for change: Data Entry Error	(b) (4)	
	Crystal Paccione (b) (4)	08 Apr 2021 20:13:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 12:33:03
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	02 Dec 2020 12:32:34
Coding entries removed.	gail lavine (b) (4)	02 Dec 2020 12:32:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:19:50

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 22:07:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 22:07:50
Data point term sent to Coder	System	03 Nov 2020 22:07:04
User entered 'ZOSYN'	douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:00:21
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:52:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:51:55
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:10:21
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Un-verified.	gail lavine (b) (4)	02 Dec 2020 12:32:16
User entered 'Small bowel obstruction' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 12:32:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:20:18
User entered 'ANTIBIOTIC'	douglas winter (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:06:13
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	08 Apr 2021 20:13:19
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 04:01:19
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit field, or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 10:00:24
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit field, or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:52:12
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit field, or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:11:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:20:20
User entered '250'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
Crystal Paccione (b) (4)	(b) (4)	08 Apr 2021 20:12:58
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 13:51:55
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:51:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:20:22
User entered 'mL (mL)'	douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:20:23
User entered empty.	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'once (ONCE)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:20:32
User entered '4 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:20:35
User entered '0'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:20:38
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:20:41
User entered '4 Oct 2020'	douglas winter (b) (4) (b) (4)	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	03 Nov 2020 22:06:24
	(b) (4)	

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User entered empty.	System	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User entered empty.	System	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:02
User entered empty.	System	03 Nov 2020 22:06:24

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:15:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:15:37
Data point term sent to Coder	System	10 Nov 2020 14:52:32
User entered 'INFLUENZA VACCINE'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'INFLUENZA PROPHYLAXIS'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0.5'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'mL (mL)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'once (ONCE)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered empty.	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '16 Oct 2020'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '0'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered '16 Oct 2020'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:05:00
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User entered empty.	System	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User entered empty.	System	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:05
User entered empty.	System	10 Nov 2020 14:51:47

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:06:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:09:32
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 14:09:31
User closed query 'Per medical records, subject had exploratory laparotomy performed. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:09:26
Query 'Per medical records, subject had exploratory laparotomy performed. Please verify and update accordingly.' answered with 'THIS HAS ALREADY BEEN UPDATED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:12:37
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Nov 2020 14:32:45
User opened query 'Per medical records, subject had exploratory laparotomy performed. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:47:12
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	10 Oct 2020 00:12:55

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '4 Oct 2020'	douglas winter (b) (4)	04 Nov 2020 14:44:19
	(b) (4)	

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered 'EXPLORATORY LAPAROTOMY'	Albert Garcia (b) (4)	10 Nov 2020 20:12:51
reason for change: Data Entry Error	(b) (4)	
User entered 'laparotomy'	douglas winter (b) (4)	04 Nov 2020 14:44:19
	(b) (4)	

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 14:44:19

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:41

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 14:44:19
	(b) (4)	

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:06:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:40
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '03 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:38:51

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:06:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:40
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'cat scan of abdomen and pelvis'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:38:51

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:40
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:38:51

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:06:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:40
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:38:51

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:06:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '03 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:44:14

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:06:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'X-ray Abdomen flat/upright with chest'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:44:14

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:06:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:44:14

US3222299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:06:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 12:44:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '12/Oct/2020 12:57'	(b) (4) System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '22/Oct/2020 15:17'	(b) (4) System	22 Oct 2020 15:17:50

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:17:32
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 15:17:50

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '04/Nov/2020 11:17'	(b) (4) System	04 Nov 2020 16:17:48

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 13:28:05
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 16:17:48

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '05/Nov/2020 13:28'	(b) (4) System	05 Nov 2020 13:28:17

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:37:11
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 13:28:17

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'USA-US104-2020-MRNA-1273-P301000010'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Yes (Y)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'No (N)'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Lisa'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Tracy'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Bruce' reason for change: Data Entry	douglas winter (b) (4)	21 Oct 2020 13:33:23
Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Tracy'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Holloway'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered 'Kowalski'	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
Un-reviewed for Safety.	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:57:06
User entered 'Kowalski'	System	12 Oct 2020 12:55:58

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '6550 Mapleridge Street'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'Houston'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Deland'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered 'TX'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'Florida'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 14:37:24
User entered '77081'	System	03 Dec 2020 14:37:24
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:17:32
Un-reviewed for Safety.	System	22 Oct 2020 15:17:50
User entered empty.	System	22 Oct 2020 15:17:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered '32720'	douglas winter (b) (4)	21 Oct 2020 13:33:23
	(b) (4)	

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:16:45
User entered 'US'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
	(b) (4)	
User entered '5'	System	03 Dec 2020 14:37:24
User entered '4'	System	05 Nov 2020 13:28:17
User entered '3'	System	04 Nov 2020 16:17:48
User entered '2'	System	22 Oct 2020 15:17:50
User entered '1'	System	12 Oct 2020 12:57:14

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:06:41

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered '03/Dec/2020 09:37'	(b) (4) System	03 Dec 2020 14:37:24

US3222299

Folder: SAE USA-US104-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:06:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:38:41
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:37:24