

US3342199 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:10:41

All time stamps listed in this document are displayed in GMT

US3342199

Form: Participant Creation

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

[Participant ID](#)

US3342199

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

US3342199

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:24:09

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 15:24:08

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Condition	CANCER OF THE KIDNEY (ENCAPSULATED TUMOR)
Start date (dd MMM yyyy)	UN JUN 2019
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)	24 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Condition	TUMOR REMOVAL RIGHT KIDNEY
Start date (dd MMM yyyy)	24 AUG 2019
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)	24 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Condition	HERPES SIMPLEX VIRUS TYPE 1
Start date (dd MMM yyyy)	24 AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342199

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Condition	HEMOCHROMATOSIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:24:09

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:58 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:58
Height (<i>xxx.x</i>)	179.0 cm
Weight (<i>xxx.x</i>)	87.2 kg
BMI (<i>xxx.x</i>)	27.21513 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:08

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111835

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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)	4 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 16:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:50:34

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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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:28

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	15:02 (24 HR)
Collection date and time (derived)	4 SEP 2020 15:02

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:04	4 SEP 2020 15:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 04 SEP 2020 16:02

PC Open Date & Time 04 SEP 2020 15:48

PC Close Date & Time 04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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 98.1 °F

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

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

PC Time Stamp	04 SEP 2020 21:16
PC Open Date & Time	04 SEP 2020 19:13
PC Close Date & Time	05 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °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	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:25

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 22:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:06

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

04 SEP 2020 16:03

PC Open Date & Time

04 SEP 2020 15:48

PC Close Date & Time

04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

04 SEP 2020 21:17

PC Open Date & Time

04 SEP 2020 19:13

PC Close Date & Time

05 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

05 SEP 2020 22:44

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

06 SEP 2020 12:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

07 SEP 2020 21:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

08 SEP 2020 18:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

09 SEP 2020 22:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

10 SEP 2020 12:06

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 16:03
PC Open Date & Time	04 SEP 2020 15:48
PC Close Date & Time	04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:18
PC Open Date & Time	04 SEP 2020 19:13
PC Close Date & Time	05 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

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 ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:44
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

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 ☒

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EAB) (1725)

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:00
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

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 ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

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 ☒

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EAB) (1725)

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US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

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
EAB) (1725)

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US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:53
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

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 ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:06
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

11 SEP 2020 13:33

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

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	11 SEP 2020 13:34
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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)	1 OCT 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 15:19
Temperature (xxx.x)	98.8 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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)	1 OCT 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 16:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 16:04

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

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	15:51 (24 HR)
Collection date and time (derived)	1 OCT 2020 15:51

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:53	1 OCT 2020 15:53
Nasopharyngeal Swab 2	No		

US3342199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

01 OCT 2020 16:39

PC Open Date & Time

01 OCT 2020 16:24

PC Close Date & Time

01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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 98.2 °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	01 OCT 2020 20:42
PC Open Date & Time	01 OCT 2020 19:49
PC Close Date & Time	02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:00

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 03 OCT 2020 12:10

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 20:38

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 13:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

97.7 °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

06 OCT 2020 20:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

01 OCT 2020 16:39

PC Open Date & Time

01 OCT 2020 16:24

PC Close Date & Time

01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

01 OCT 2020 20:42

PC Open Date & Time

01 OCT 2020 19:49

PC Close Date & Time

02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

03 OCT 2020 12:11

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

04 OCT 2020 20:38

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

05 OCT 2020 13:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

06 OCT 2020 20:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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 ☐

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 16:40
PC Open Date & Time	01 OCT 2020 16:24
PC Close Date & Time	01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 20:43
PC Open Date & Time	01 OCT 2020 19:49
PC Close Date & Time	02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

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 ☒

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

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 ☒

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EAB) (1725)

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US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

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 ☒

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:39
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

EAB) (1725)

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US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 13:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

EAB) (1725)

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US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:33
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

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)

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US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

Yes ☐

PC Time stamp

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:28

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:29

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:06 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:06
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

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.

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	14:47 (24 HR)
Collection date and time (derived)	28 OCT 2020 14:47

US3342199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:34

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	06 NOV 2020 12:01:09
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 17:18:27

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 13:19:28

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	06 DEC 2020 22:21:43
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

13 DEC 2020 08:17:44

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:01:32

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

27 DEC 2020 12:33:37

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 12:00:58

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 12:00:49

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	18 JAN 2021 08:13:02
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 17:13:25

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 22:13:32

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	08 FEB 2021 09:58:09
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 10:32:25

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

21 FEB 2021 09:09:30

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 12:23:59

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 MAR 2021 07:34:35
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	16 MAR 2021 12:30:26
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

21 MAR 2021 08:27:10

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

28 MAR 2021 15:18:47

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

04 APR 2021 11:20:53

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

11 APR 2021 16:43:25

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

18 APR 2021 07:34:41

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

27 APR 2021 12:00:32

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

02 MAY 2021 07:20:56

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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

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

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAR 2022 00:01

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31 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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="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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 <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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3342199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:10:41

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 12:24:10

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:31 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 08:31
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

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.

US3342199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

08:52 (24 HR)

Collection date and time (derived)

24 MAR 2021 08:52

US3342199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:33:28

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:33:28

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

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

US3342199

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342199

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:41

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"/>

US3342199

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:10:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342199

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

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3342199

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342199

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3342199

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:25
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	15:34 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:34
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	011 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

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

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3342199

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

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 15:03 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 15:03

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

US3342199

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	14:57 (24 HR)
Collection date and time (derived)	14 JAN 2021 14:57

US3342199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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

US3342199

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

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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

US3342199

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:51:31

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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)	10 FEB 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 14:08
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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)	10 FEB 2021
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 15:03
Temperature (xxx.x)	98.4 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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.

US3342199

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 10 FEB 2021

What was the treatment time? (00:00-23:59) 14:33 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 14:33

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

US3342199

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:31 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 08:31
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342199

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

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.

US3342199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

08:52 (24 HR)

Collection date and time (derived)

24 MAR 2021 08:52

US3342199

Folder: Unscheduled (2)

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:10:41

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Visit Date	10 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:07:50

Generated On: 09 Jun 2021 17:10:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	10 FEB 2021 14:25

US3342199

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 16:37:48

Generated On: 09 Jun 2021 17:10:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

AEID	USA-US203-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE FOCAL COLITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 SEP 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)	25 SEP 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)	13 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	15 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020. SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020. CT OF ABDOMEN/PELVIC SHOWED 3CM SEGMENT OF CIRCUMFERENTIAL BOWEL WALL THICKENING IN THE SIGMOID COLON WITH SIGNIFICANT PERISEROSAL INFLAMMATORY CHANGES ALONG ITS MESENTERIC SIDE, WORRISOME FOR MALIGNANCY. DIAGNOSTIC CONSIDERATIONS ALSO INCLUDE FOCAL COLITIS. CBC LABS SHOW ELEVATED WBC AT 14.4 THOU/CU MM ON DAY OF ADMITTANCE 9/13/2020, BACK TO NORMAL VALUES OF 9.3 AND 7.4 THOU/CU MM ON 9/14/2020 AND 9/15/2020 RESPECTIVELY. RBC LEVELS LOW AT 4.05, 3.75 AND 3.52 MLL/CU MM; HGB 13.4, 12.4, 11.8 G/DL, HCT 38.3, 36.0, 34.6

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

PERCENT, MCV HIGH AT 94.6, 96.0, 98.3 FL, MCH HIGH AT 33.1, 33.1, 33.5 PG, ON 9/13/2020, 9/14/2020, AND 9/15/2020. DIFFERENTIAL PANEL SHOW HIGH NEUTRO AUTO 76.8 AND 69.8 PERCENT, AND LYMPH AUTO LOW AT 13.5 AND 18.7 PERCENT, ON 9/13/2020 AND 9/15/2020. UA ALL IN NORMAL RANGE ON 9/13/2020. ROUTINE CHEMISTRY SHOWED HIGH GLUCOSE ON 9/13/2020 AT 118MG/DL. GLUCOSE LEVELS WERE 98 AND 92 MG/DL ON 9/14/2020 AND 9/15/2020. SARSCOV2 TESTING DONE ON 9/13/2020, TARGET NUCLEIC ACIDS NOT DETECTED.

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

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

AEID

Adverse event

LYMPHADENOPATHY R SIDE
CONTRALATERAL TO
INJECTION SITE IN R AXILLAE

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)

10 FEB 2021

Start time (00:00-23:59)

19:00 (24 HR)

AE start date and time (derived)

10 FEB 2021 19:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 FEB 2021

End time (00:00-23:59)

07:00 (24 HR)

AE End Date and Time (derived)

11 FEB 2021 07:00

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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

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 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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

AEID

Adverse event

ACUTE FOCAL COLITIS #2

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)

07 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	06 SEP 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)	06 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Mar 2021 13:29:34

Generated On: 09 Jun 2021 17:10:41

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

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

Yes ☒

No ☐

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

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX VIRUS TYPE 1

Dose per administration 400

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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 AUG 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication PSEUDOEPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)	UN UNK 1985	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		13 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) 20 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:07:49

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Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		13 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) 24 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 220

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		06 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)		06 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication ACETAMINOPHEN-CODEINE

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

Dose per administration 300/30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		13 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication PIPERACILLIN/TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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)		13 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication AE ACUTE FOCAL COLITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:07:49

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	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)		13 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication MAINTAINENCE DRUG FOR
POST PARTIAL NEPHRECTOMY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication YEARLY FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication YEARLY FLU PREVENTION

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)		9 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE FOCAL COLITIS #2 AE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACUTE FOCAL COLITIS #2 AE

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

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EAB) (1725)

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Mar 2021 15:07:49

Generated On: 09 Jun 2021 17:10:41

	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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 SEP 2020	CT SCAN ABDOMEN/PELVIS	Adverse Event	
15 SEP 2020	CBC LABS	Adverse Event	
13 SEP 2020	CBC LABS	Adverse Event	
15 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
14 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
13 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
25 SEP 2020	COLONOSCOPY	Adverse Event	

US3342199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:10:41

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

US3342199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:10:41

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 ☐

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:32
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

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:49
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

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/OCT/2020 08:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Mar 2021 15:24:08

Generated On: 09 Jun 2021 17:10:41

SAEID	USA-US203-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3342199 (Prod: Tekton Research- Austin)

US3342199

Form: Participant Creation

Generated On: 09 Jun 2021 17:10:41

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:10:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'US3342199'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:27

US3342199

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:59:23

US3342199

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:28

US3342199

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 19:59:23

US3342199

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'SCRN'	System	04 Sep 2020 19:59:23

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:29

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '59'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'YEARS'	System	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '59'	System	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'Male (M)'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Sep 2020'	System	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2020'	System	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:28

US3342199

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'I'	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:10:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:05:41

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Renal cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:59:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:59:46
Data point term sent to Coder	System	04 Sep 2020 20:36:01
User entered 'cancer of the kidney (encapsulated tumor)'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'un Jun 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Jun 2019'	System	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2019'	System	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Aug 2019'	System	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2019'	System	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal tumour excision, LLT: Renal tumor excision - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:29:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:29:46
Data point term sent to Coder	System	04 Sep 2020 20:36:01
User entered 'tumor removal right kidney'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Aug 2019'	System	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2019'	System	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Aug 2019'	System	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2019'	System	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:37:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:37:46
Data point term sent to Coder	System	04 Sep 2020 20:37:03
User entered 'herpes simplex virus type 1'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2015'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Aug 2015'	System	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2015'	System	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:38:20
Data point term sent to Coder	System	04 Sep 2020 20:37:04
User entered 'seasonal allergies'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'un UNK 1985'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Jan 1985'	System	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '1985'	System	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:42
Data point term sent to Coder	System	09 Oct 2020 20:25:45
User entered 'INSOMNIA'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'UN UNK 2018'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Jan 2018'	System	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2018'	System	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Iron and trace metal metabolism disorders, HLT: Iron excess, PT: Haemochromatosis, LLT: Hemochromatosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:06:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:06:31
Data point term sent to Coder	System	09 Oct 2020 20:25:46
User entered 'HEMOCHROMATOSIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'UN UNK 2018'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'Jan 2018'	System	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '2018'	System	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered empty.	System	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '13:58'	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '4 Sep 2020 13:58'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '179.0' cm	(b) (4), (b) (6)	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '87.2' kg	(b) (4), (b) (6)	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered '27.21513'	System	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'kg/m2'	System	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'bpm'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'breaths/min'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'mmHg'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User entered 'mmHg'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12

US3342199

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:06:41

US3342199

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:00
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:06:41

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	09 Sep 2020 21:00:57
User entered '0' reason for change: Data Entry Error John Luna	(b) (4)	09 Sep 2020 21:00:57
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:07:21
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:17:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered '04 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 17:00:07
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'VISIT1'	System	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '111835'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:41

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:14:40
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Answered' (Site from DM).	Olivia Hapanowicz (b) (4)	03 Dec 2020 23:29:20
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	03 Dec 2020 23:29:16
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:56:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:28:59

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:10:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:10:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '4 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '13:59' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '4 Sep 2020 13:59'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 21:10:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'bpm'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'breaths/min'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.		04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:10:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:10:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '4 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '16:00' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '4 Sep 2020 16:00'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 21:10:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:52
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'bpm'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'breaths/min'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '149' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:06
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:08:13

US3342199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:06
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:13

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered '15:28'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '4 Sep 2020 15:28'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'ONCE'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:18
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:18
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:58:59
User entered '15:02' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:58:59
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:09:19
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '4 Sep 2020 15:02'	System	08 Sep 2020 20:58:59
User entered empty.	System	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:25
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 20:58:49
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 20:58:49
User entered '15:04' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:58:49
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:09:30
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '4 Sep 2020 15:04'	System	08 Sep 2020 20:58:49
User entered empty.	System	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:25
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:58:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 20:58:49
User entered 'No (N)' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:58:49
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:09:30
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered empty.	System	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:30:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:38

US3342199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	04 Sep 2020 20:09:38

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc' User entered 'Yes (Y)'	System	04 Sep 2020 21:02:37
	System	04 Sep 2020 21:02:37

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc' User entered '98.1'	System	04 Sep 2020 21:02:37
	System	04 Sep 2020 21:02:37

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc' User entered 'No (N)'	System	04 Sep 2020 21:02:37
	System	04 Sep 2020 21:02:37

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc' User entered '04 Sep 2020 16:02'	System	04 Sep 2020 21:02:37
	System	04 Sep 2020 21:02:37

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d' User entered 'Yes (Y)'	System	05 Sep 2020 02:16:53
	System	05 Sep 2020 02:16:53

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d' User entered '98.1'	System	05 Sep 2020 02:16:53
	System	05 Sep 2020 02:16:53

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d' User entered 'No (N)'	System	05 Sep 2020 02:16:53
	System	05 Sep 2020 02:16:53

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d' User entered '04 Sep 2020 21:16'	System	05 Sep 2020 02:16:53
	System	05 Sep 2020 02:16:53

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473' User entered 'Yes (Y)'	System	06 Sep 2020 03:47:01
	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473' User entered '96.8'	System	06 Sep 2020 03:47:01
	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473' User entered 'No (N)'	System	06 Sep 2020 03:47:01
	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473' User entered '05 Sep 2020 22:46'	System	06 Sep 2020 03:47:01
	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered 'Yes (Y)'	System	06 Sep 2020 17:02:01
	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered '98.1'	System	06 Sep 2020 17:02:01
	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered 'Yes (Y)'	System	06 Sep 2020 17:02:01
	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
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 'data entered' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:22:52
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 (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered '1'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:04:53
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).	System	06 Sep 2020 17:02:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered '1'	System	06 Sep 2020 17:02:01
User entered '1'	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered '0'	System	06 Sep 2020 17:02:01
	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0' User entered '06 Sep 2020 12:01'	System	06 Sep 2020 17:02:01
	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:23:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3' User entered 'Yes (Y)'	System	08 Sep 2020 02:24:07
	System	08 Sep 2020 02:24:07

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:23:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3' User entered '97.8'	System	08 Sep 2020 02:24:07
	System	08 Sep 2020 02:24:07

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3' User entered 'No (N)'	System	08 Sep 2020 02:24:07
	System	08 Sep 2020 02:24:07

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3' User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:07
	System	08 Sep 2020 02:24:07

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3' User entered 'Yes (Y)'	System	08 Sep 2020 23:26:01
	System	08 Sep 2020 23:26:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3' User entered '97.8'	System	08 Sep 2020 23:26:01
	System	08 Sep 2020 23:26:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3'	System	08 Sep 2020 23:26:01
User entered 'No (N)'	System	08 Sep 2020 23:26:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3' User entered '08 Sep 2020 18:25'	System	08 Sep 2020 23:26:01
	System	08 Sep 2020 23:26:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:52:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17' User entered 'Yes (Y)'	System	10 Sep 2020 03:53:04
	System	10 Sep 2020 03:53:04

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:52:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17' User entered '97.8'	System	10 Sep 2020 03:53:04
	System	10 Sep 2020 03:53:04

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17' User entered 'No (N)'	System	10 Sep 2020 03:53:04
	System	10 Sep 2020 03:53:04

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17' User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:04
	System	10 Sep 2020 03:53:04

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered 'Yes (Y)'	System	10 Sep 2020 17:06:21
	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered '98.3'	System	10 Sep 2020 17:06:21
	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered 'No (N)'	System	10 Sep 2020 17:06:21
	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:21
	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c' User entered 'None (1)'	System	04 Sep 2020 21:03:32
	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:12', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c' User entered 'No (N)'	System	04 Sep 2020 21:03:32
	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c' User entered 'No (N)'	System	04 Sep 2020 21:03:32
	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c' User entered 'None (1)'	System	04 Sep 2020 21:03:32
	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c' User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:03:32
	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered 'None (1)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfcb8142' User entered 'No (N)'	System	05 Sep 2020 02:17:40
	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered 'No (N)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered 'None (1)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered '04 Sep 2020 21:17'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'None (1)'	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5' User entered 'No (N)'	System	06 Sep 2020 03:44:17
	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'No (N)'	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'None (1)'	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5' User entered '05 Sep 2020 22:44'	System	06 Sep 2020 03:44:17
	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered 'None (1)'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered 'No (N)'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered 'No (N)'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered 'None (1)'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-ae4-cb57c14c348f' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered 'None (1)'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:12', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered 'No (N)'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered 'No (N)'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered 'None (1)'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3' User entered 'None (1)'	System	08 Sep 2020 23:26:16
	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3' User entered 'No (N)'	System	08 Sep 2020 23:26:16
	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3' User entered 'No (N)'	System	08 Sep 2020 23:26:16
	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3' User entered 'None (1)'	System	08 Sep 2020 23:26:16
	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3' User entered '08 Sep 2020 18:26'	System	08 Sep 2020 23:26:16
	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered 'None (1)'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered 'No (N)'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered 'No (N)'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered 'None (1)'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb' User entered 'None (1)'	System	10 Sep 2020 17:06:32
	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb' User entered 'No (N)'	System	10 Sep 2020 17:06:32
	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb' User entered 'No (N)'	System	10 Sep 2020 17:06:32
	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered 'None (1)'	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:30', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb' User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:32
	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'None (0)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered 'No (N)'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:18:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'No (N)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:18:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered '04 Sep 2020 21:18'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'None (0)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered 'No (N)'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602' User entered '05 Sep 2020 22:44'	System	06 Sep 2020 03:44:37
	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'None (0)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered 'No (N)'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:01:17
	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'None (0)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered 'No (N)'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:46', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7' User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:51
	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'None (0)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered 'No (N)'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5' User entered '08 Sep 2020 18:26'	System	08 Sep 2020 23:26:39
	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'No (N)'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:37
	System	10 Sep 2020 03:53:37

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'No interference with activity (1)'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'None (0)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:40', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'None (0)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'None (0)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'None (0)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'None (0)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered 'No (N)'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90' User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:57
	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	10 Sep 2020 17:06:57
User entered 'Day 8'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:33:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3249b83c-917e-4fb7-88e8-c4a976e543bc' User entered 'None (0)'	System	11 Sep 2020 18:33:59
	System	11 Sep 2020 18:33:59

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:33:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3249b83c-917e-4fb7-88e8-c4a976e543bc' User entered '11 Sep 2020 13:33'	System	11 Sep 2020 18:33:59
	System	11 Sep 2020 18:33:59

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	10 Sep 2020 17:06:57
User entered 'Day 8'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:34:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'aad25c6a-e91c-4eaa-b633-b0a60bb841e0' User entered 'No (N)'	System	11 Sep 2020 18:34:04
	System	11 Sep 2020 18:34:04

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:34:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'aad25c6a-e91c-4eaa-b633-b0a60bb841e0' User entered '11 Sep 2020 13:34'	System	11 Sep 2020 18:34:04
	System	11 Sep 2020 18:34:04

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:06:57

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '11 Sep 2020'	Ethan Shotton (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	Ethan Shotton (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Sep 2020 18:45:47

US3342199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	11 Sep 2020 18:45:47

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:03

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:03

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:03

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:03

US3342199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:07

US3342199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User entered 'I'	System	18 Sep 2020 18:29:07

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	30 Sep 2020 13:23:33

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '28 Sep 2020'	Eileen Euperio (b) (4)	30 Sep 2020 13:23:33

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4)	30 Sep 2020 13:23:33

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	Eileen Euperio (b) (4)	30 Sep 2020 13:23:33

US3342199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	30 Sep 2020 13:23:39

US3342199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User entered 'I'	System	30 Sep 2020 13:23:39

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '1 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'VISIT2'	System	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '15:19'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '1 Oct 2020 15:19'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '98.8' F	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '64'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'bpm'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '14'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'breaths/min'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '133'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '76'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '16:36'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '1 Oct 2020 16:36'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '98.0' F	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '59'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'bpm'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '12'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'breaths/min'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '114'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '68'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:52
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:57

US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:52
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:57

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered '16:04'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '1 Oct 2020 16:04'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'ONCE'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered '15:51'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '1 Oct 2020 15:51'	System	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered '15:53'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '1 Oct 2020 15:53'	System	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered empty.	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered empty.	System	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:53:02

US3342199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	01 Oct 2020 20:53:02

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:38:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c' User entered 'Yes (Y)'	System	01 Oct 2020 21:39:18
	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c' User entered '98.0'	System	01 Oct 2020 21:39:18
	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c'	System	01 Oct 2020 21:39:18
User entered 'No (N)'	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c' User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:39:18
	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5' User entered 'Yes (Y)'	System	02 Oct 2020 01:42:37
	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5' User entered '98.2'	System	02 Oct 2020 01:42:37
	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5' User entered 'No (N)'	System	02 Oct 2020 01:42:37
	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5' User entered '01 Oct 2020 20:42'	System	02 Oct 2020 01:42:37
	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224' User entered 'Yes (Y)'	System	02 Oct 2020 17:00:54
	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:37', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224' User entered '97.1'	System	02 Oct 2020 17:00:54
	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224' User entered 'No (N)'	System	02 Oct 2020 17:00:54
	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224' User entered '02 Oct 2020 12:00'	System	02 Oct 2020 17:00:54
	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:30', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3' User entered 'Yes (Y)'	System	03 Oct 2020 17:10:51
	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3' User entered '98.7'	System	03 Oct 2020 17:10:51
	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:46', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3'	System	03 Oct 2020 17:10:51
User entered 'No (N)'	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3' User entered '03 Oct 2020 12:10'	System	03 Oct 2020 17:10:51
	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282' User entered 'Yes (Y)'	System	05 Oct 2020 01:38:33
	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282' User entered '98.1'	System	05 Oct 2020 01:38:33
	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282' User entered 'No (N)'	System	05 Oct 2020 01:38:33
	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282' User entered '04 Oct 2020 20:38'	System	05 Oct 2020 01:38:33
	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered 'Yes (Y)'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered '97.8'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:40', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered 'No (N)'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered '05 Oct 2020 13:18'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:31:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043' User entered 'Yes (Y)'	System	07 Oct 2020 01:33:23
	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043' User entered '97.7'	System	07 Oct 2020 01:33:23
	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043' User entered 'No (N)'	System	07 Oct 2020 01:33:23
	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043' User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:23
	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'None (1)'	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775' User entered 'No (N)'	System	01 Oct 2020 21:39:50
	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'No (N)'	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775' User entered 'None (1)'	System	01 Oct 2020 21:39:50
	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775' User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:39:50
	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8' User entered 'None (1)'	System	02 Oct 2020 01:43:01
	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8' User entered 'No (N)'	System	02 Oct 2020 01:43:01
	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8' User entered 'No (N)'	System	02 Oct 2020 01:43:01
	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8' User entered 'None (1)'	System	02 Oct 2020 01:43:01
	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8' User entered '01 Oct 2020 20:42'	System	02 Oct 2020 01:43:01
	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered 'None (1)'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered 'No (N)'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered 'No (N)'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered 'None (1)'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered 'None (1)'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered 'No (N)'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered 'No (N)'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered 'None (1)'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered '03 Oct 2020 12:11'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered 'None (1)'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered 'No (N)'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered 'No (N)'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered 'None (1)'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered '04 Oct 2020 20:38'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'None (1)'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'No (N)'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'No (N)'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'None (1)'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered '05 Oct 2020 13:18'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'None (1)'	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85' User entered 'No (N)'	System	07 Oct 2020 01:33:31
	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85' User entered 'No (N)'	System	07 Oct 2020 01:33:31
	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'None (1)'	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85' User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:31
	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'No (N)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered '01 Oct 2020 16:40'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'No (N)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered '01 Oct 2020 20:43'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:20', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'No (N)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:16', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'No (N)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered '03 Oct 2020 12:11'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'No (N)'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered '04 Oct 2020 20:39'	System	05 Oct 2020 01:39:07
	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'None (0)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered 'No (N)'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05' User entered '05 Oct 2020 13:19'	System	05 Oct 2020 18:19:12
	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'None (0)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered 'No (N)'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

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)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Oct 2020 18:30:10

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '8 Oct 2020'	Eileen Euperio (b) (4)	09 Oct 2020 18:30:10

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4)	09 Oct 2020 18:30:10

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	Eileen Euperio (b) (4)	09 Oct 2020 18:30:10

US3342199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Oct 2020 18:30:15

US3342199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User entered 'I'	System	09 Oct 2020 18:30:15

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:03:49

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:03:49

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:03:49

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:03:49

US3342199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:03:54

US3342199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:34
User entered 'I'	System	16 Oct 2020 15:03:54

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:55:18

US3342199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	23 Oct 2020 15:55:18

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:39:51

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:39:51

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:39:51

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'VISIT3'	System	28 Oct 2020 19:39:51

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '14:06'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '28 Oct 2020 14:06'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '60'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'bpm'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '14'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'breaths/min'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '146'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '90'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'mmHg'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:41:02

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:41:02

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 09:28:16
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' answered with 'collection date was 28OCT2020' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:56:09
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:32:48
User entered '28 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered '14:47'	Morgan Schulle (b) (4)	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered '28 Oct 2020 14:47'	System	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:41:06

US3342199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	28 Oct 2020 19:41:06

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 64'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:00:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304' User entered 'No (N)'	System	06 Nov 2020 18:01:39
	System	06 Nov 2020 18:01:39

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:01:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304' User entered 'No (N)'	System	06 Nov 2020 18:01:39
	System	06 Nov 2020 18:01:39

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:01:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304' User entered '06 Nov 2020 12:01:09'	System	06 Nov 2020 18:01:39
	System	06 Nov 2020 18:01:39

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:05
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 71'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 78'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 20:37:32

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:18
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 20:37:32

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:16', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111' User entered 'No (N)'	System	23 Nov 2020 23:18:30
	System	23 Nov 2020 23:18:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111' User entered 'No (N)'	System	23 Nov 2020 23:18:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111' User entered '23 Nov 2020 17:18:27'	System	23 Nov 2020 23:18:30
	System	23 Nov 2020 23:18:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-29T13:19:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a5dabace-1352-4fa6-a6db-055b50a9315b'	System	29 Nov 2020 19:19:30
User entered 'No (N)'	System	29 Nov 2020 19:19:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-29T13:19:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a5dabace-1352-4fa6-a6db-055b50a9315b'	System	29 Nov 2020 19:19:30
User entered 'No (N)'	System	29 Nov 2020 19:19:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-29T13:19:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a5dabace-1352-4fa6-a6db-055b50a9315b' User entered '29 Nov 2020 13:19:28'	System	29 Nov 2020 19:19:30
	System	29 Nov 2020 19:19:30

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-06T22:21:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '501e082a-a435-4f50-b58f-05d9ff649be0' User entered 'No (N)'	System	07 Dec 2020 04:21:50
	System	07 Dec 2020 04:21:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-06T22:21:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '501e082a-a435-4f50-b58f-05d9ff649be0' User entered 'No (N)'	System	07 Dec 2020 04:21:50
	System	07 Dec 2020 04:21:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-06T22:21:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '501e082a-a435-4f50-b58f-05d9ff649be0' User entered '06 Dec 2020 22:21:43'	System	07 Dec 2020 04:21:50
	System	07 Dec 2020 04:21:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-13T08:17:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '48a554bb-2d8d-4886-99bb-90d6966f3286'	System	13 Dec 2020 14:17:47
User entered 'No (N)'	System	13 Dec 2020 14:17:47

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-13T08:17:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '48a554bb-2d8d-4886-99bb-90d6966f3286'	System	13 Dec 2020 14:17:47
User entered 'No (N)'	System	13 Dec 2020 14:17:47

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-13T08:17:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '48a554bb-2d8d-4886-99bb-90d6966f3286' User entered '13 Dec 2020 08:17:44'	System	13 Dec 2020 14:17:47
	System	13 Dec 2020 14:17:47

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-20T00:01:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '450302d8-7f4f-401d-a6f4-d46f9ae4ff91' User entered 'No (N)'	System	20 Dec 2020 06:01:38
	System	20 Dec 2020 06:01:38

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-20T00:01:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '450302d8-7f4f-401d-a6f4-d46f9ae4ff91' User entered 'No (N)'	System	20 Dec 2020 06:01:38
	System	20 Dec 2020 06:01:38

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-20T00:01:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '450302d8-7f4f-401d-a6f4-d46f9ae4ff91'	System	20 Dec 2020 06:01:38
User entered '20 Dec 2020 00:01:32'	System	20 Dec 2020 06:01:38

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-27T12:33:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b1c9b828-1373-4cef-a98b-ab7744485083' User entered 'No (N)'	System	27 Dec 2020 18:33:41
	System	27 Dec 2020 18:33:41

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-27T12:33:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b1c9b828-1373-4cef-a98b-ab7744485083' User entered 'No (N)'	System	27 Dec 2020 18:33:41
	System	27 Dec 2020 18:33:41

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-12-27T12:33:37', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b1c9b828-1373-4cef-a98b-ab7744485083' User entered '27 Dec 2020 12:33:37'	System	27 Dec 2020 18:33:41
	System	27 Dec 2020 18:33:41

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-05T12:00:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f12995e5-ae9b-4fca-b379-3e81d3510a5e'	System	05 Jan 2021 18:01:19
User entered 'No (N)'	System	05 Jan 2021 18:01:19

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-05T12:00:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f12995e5-ae9b-4fca-b379-3e81d3510a5e'	System	05 Jan 2021 18:01:19
User entered 'No (N)'	System	05 Jan 2021 18:01:19

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-05T12:00:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f12995e5-ae9b-4fca-b379-3e81d3510a5e' User entered '05 Jan 2021 12:00:58'	System	05 Jan 2021 18:01:19
	System	05 Jan 2021 18:01:19

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-12T12:00:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '27761012-7663-4dff-a2ae-8143a3370307'	System	12 Jan 2021 18:01:23
User entered 'No (N)'	System	12 Jan 2021 18:01:23

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-12T12:00:46', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '27761012-7663-4dff-a2ae-8143a3370307'	System	12 Jan 2021 18:01:23
User entered 'No (N)'	System	12 Jan 2021 18:01:23

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-12T12:00:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '27761012-7663-4dff-a2ae-8143a3370307' User entered '12 Jan 2021 12:00:49'	System	12 Jan 2021 18:01:23
	System	12 Jan 2021 18:01:23

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-18T08:12:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '679559a3-64e9-45ca-b529-3d35fdcf0569'	System	18 Jan 2021 14:13:05
User entered 'No (N)'	System	18 Jan 2021 14:13:05

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-18T08:12:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '679559a3-64e9-45ca-b529-3d35fdcf0569'	System	18 Jan 2021 14:13:05
User entered 'No (N)'	System	18 Jan 2021 14:13:05

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-18T08:13:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '679559a3-64e9-45ca-b529-3d35fdcf0569' User entered '18 Jan 2021 08:13:02'	System	18 Jan 2021 14:13:05
	System	18 Jan 2021 14:13:05

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-25T17:13:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c18a7e8-6c0f-47c4-9a99-f07229d03719'	System	25 Jan 2021 23:13:28
User entered 'No (N)'	System	25 Jan 2021 23:13:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-25T17:13:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c18a7e8-6c0f-47c4-9a99-f07229d03719'	System	25 Jan 2021 23:13:28
User entered 'No (N)'	System	25 Jan 2021 23:13:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-25T17:13:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c18a7e8-6c0f-47c4-9a99-f07229d03719' User entered '25 Jan 2021 17:13:25'	System	25 Jan 2021 23:13:28
	System	25 Jan 2021 23:13:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-31T22:13:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e797fca2-9e4b-43cc-8f46-e010935edaf9' User entered 'No (N)'	System	01 Feb 2021 04:13:36
	System	01 Feb 2021 04:13:36

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-31T22:13:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e797fca2-9e4b-43cc-8f46-e010935edaf9' User entered 'No (N)'	System	01 Feb 2021 04:13:36

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-01-31T22:13:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e797fca2-9e4b-43cc-8f46-e010935edaf9' User entered '31 Jan 2021 22:13:32'	System	01 Feb 2021 04:13:36
	System	01 Feb 2021 04:13:36

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-08T09:58:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4c4ee9f6-4b30-4dc0-83d4-c54ffc4aba5d' User entered 'No (N)'	System	08 Feb 2021 15:58:13
	System	08 Feb 2021 15:58:13

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-08T09:58:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4c4ee9f6-4b30-4dc0-83d4-c54ffc4aba5d' User entered 'No (N)'	System	08 Feb 2021 15:58:13

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-08T09:58:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4c4ee9f6-4b30-4dc0-83d4-c54ffc4aba5d' User entered '08 Feb 2021 09:58:09'	System	08 Feb 2021 15:58:13
	System	08 Feb 2021 15:58:13

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-14T10:32:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3f37b533-603f-40ab-9758-f70e4fee45c7'	System	14 Feb 2021 16:32:27
User entered 'No (N)'	System	14 Feb 2021 16:32:27

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-14T10:32:20', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3f37b533-603f-40ab-9758-f70e4fee45c7'	System	14 Feb 2021 16:32:27
User entered 'No (N)'	System	14 Feb 2021 16:32:27

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-14T10:32:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3f37b533-603f-40ab-9758-f70e4fee45c7'	System	14 Feb 2021 16:32:27
User entered '14 Feb 2021 10:32:25'	System	14 Feb 2021 16:32:27

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-21T09:09:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7b3513e9-47f9-4300-aedb-06b32f51faef' User entered 'No (N)'	System	21 Feb 2021 15:09:32
	System	21 Feb 2021 15:09:32

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-21T09:09:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7b3513e9-47f9-4300-aedb-06b32f51faef' User entered 'No (N)'	System	21 Feb 2021 15:09:32
	System	21 Feb 2021 15:09:32

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-02-21T09:09:30', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7b3513e9-47f9-4300-aedb-06b32f51faef' User entered '21 Feb 2021 09:09:30'	System	21 Feb 2021 15:09:32
	System	21 Feb 2021 15:09:32

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-04T12:23:54-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ebb758b3-8638-4fe7-847c-549432f46d61'	System	04 Mar 2021 18:24:03
User entered 'No (N)'	System	04 Mar 2021 18:24:03

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-04T12:23:56-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ebb758b3-8638-4fe7-847c-549432f46d61'	System	04 Mar 2021 18:24:03
User entered 'No (N)'	System	04 Mar 2021 18:24:03

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-04T12:23:59-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ebb758b3-8638-4fe7-847c-549432f46d61'	System	04 Mar 2021 18:24:03
User entered '04 Mar 2021 12:23:59'	System	04 Mar 2021 18:24:03

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:00-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0'	System	08 Mar 2021 13:34:45
User entered 'Yes (Y)'	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:03-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0'	System	08 Mar 2021 13:34:45
User entered 'No (N)'	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:09-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0'	System	08 Mar 2021 13:34:45
User entered 'No (N)'	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:18-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0'	System	08 Mar 2021 13:34:45
User entered 'Yes (Y)'	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:30-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0'	System	08 Mar 2021 13:34:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-08T07:34:35-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'afa7fe05-7696-4896-8ed2-982c0e918ab0' User entered '08 Mar 2021 07:34:35'	System	08 Mar 2021 13:34:45
	System	08 Mar 2021 13:34:45

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-16T12:30:21-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b842acb2-aeda-4e57-9c3f-2f6baeced823'	System	16 Mar 2021 17:30:35
User entered 'No (N)'	System	16 Mar 2021 17:30:35

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-16T12:30:23-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b842acb2-aeda-4e57-9c3f-2f6baeced823'	System	16 Mar 2021 17:30:35
User entered 'No (N)'	System	16 Mar 2021 17:30:35

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-16T12:30:26-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b842acb2-aeda-4e57-9c3f-2f6baeced823'	System	16 Mar 2021 17:30:35
User entered '16 Mar 2021 12:30:26'	System	16 Mar 2021 17:30:35

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-21T08:27:04-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5c5dde7c-f768-4819-a3cf-28501d2df311'	System	21 Mar 2021 13:27:12
User entered 'No (N)'	System	21 Mar 2021 13:27:12

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-21T08:27:07-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5c5dde7c-f768-4819-a3cf-28501d2df311'	System	21 Mar 2021 13:27:12
User entered 'No (N)'	System	21 Mar 2021 13:27:12

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-21T08:27:10-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5c5dde7c-f768-4819-a3cf-28501d2df311'	System	21 Mar 2021 13:27:12
User entered '21 Mar 2021 08:27:10'	System	21 Mar 2021 13:27:12

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-28T15:18:40-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82b20c17-aeb3-459e-846c-18a2f6fb648c'	System	28 Mar 2021 20:18:50
User entered 'No (N)'	System	28 Mar 2021 20:18:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-28T15:18:45-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82b20c17-aeb3-459e-846c-18a2f6fb648c'	System	28 Mar 2021 20:18:50
User entered 'No (N)'	System	28 Mar 2021 20:18:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-28T15:18:47-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82b20c17-aeb3-459e-846c-18a2f6fb648c' User entered '28 Mar 2021 15:18:47'	System	28 Mar 2021 20:18:50
	System	28 Mar 2021 20:18:50

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-04T11:20:47-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ec4ca5f8-9f0e-4c86-89b8-7018dcb8e749'	System	04 Apr 2021 16:21:34
User entered 'No (N)'	System	04 Apr 2021 16:21:34

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-04T11:20:50-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ec4ca5f8-9f0e-4c86-89b8-7018dcb8e749'	System	04 Apr 2021 16:21:34
User entered 'No (N)'	System	04 Apr 2021 16:21:34

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-04T11:20:53-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'ec4ca5f8-9f0e-4c86-89b8-7018dcb8e749'	System	04 Apr 2021 16:21:34
User entered '04 Apr 2021 11:20:53'	System	04 Apr 2021 16:21:34

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-11T16:43:20-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f91649f2-9c1a-4d07-a7cf-b3924be2df58'	System	11 Apr 2021 21:43:28
User entered 'No (N)'	System	11 Apr 2021 21:43:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-11T16:43:22-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f91649f2-9c1a-4d07-a7cf-b3924be2df58'	System	11 Apr 2021 21:43:28
User entered 'No (N)'	System	11 Apr 2021 21:43:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-11T16:43:25-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f91649f2-9c1a-4d07-a7cf-b3924be2df58'	System	11 Apr 2021 21:43:28
User entered '11 Apr 2021 16:43:25'	System	11 Apr 2021 21:43:28

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-18T07:34:36-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'af7736d0-24bb-46e5-8706-eb1388795d51' User entered 'No (N)'	System	29 Apr 2021 04:48:33
	System	29 Apr 2021 04:48:33

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-18T07:34:39-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'af7736d0-24bb-46e5-8706-eb1388795d51'	System	29 Apr 2021 04:48:33
User entered 'No (N)'	System	29 Apr 2021 04:48:33

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-18T07:34:41-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'af7736d0-24bb-46e5-8706-eb1388795d51'	System	29 Apr 2021 04:48:33
User entered '18 Apr 2021 07:34:41'	System	29 Apr 2021 04:48:33

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-27T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '873f2dd1-2285-4324-88ad-4971e2001b58'	System	29 Apr 2021 04:48:55
User entered 'No (N)'	System	29 Apr 2021 04:48:55

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-27T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '873f2dd1-2285-4324-88ad-4971e2001b58'	System	29 Apr 2021 04:48:55
User entered 'No (N)'	System	29 Apr 2021 04:48:55

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-04-27T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '873f2dd1-2285-4324-88ad-4971e2001b58'	System	29 Apr 2021 04:48:55
User entered '27 Apr 2021 12:00:32'	System	29 Apr 2021 04:48:55

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-05-02T07:20:50-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6b7798d5-571e-4d67-879e-18b2b993c20f' User entered 'No (N)'	System	02 May 2021 12:20:58
	System	02 May 2021 12:20:58

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

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 (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-05-02T07:20:53-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6b7798d5-571e-4d67-879e-18b2b993c20f'	System	02 May 2021 12:20:58
User entered 'No (N)'	System	02 May 2021 12:20:58

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-05-02T07:20:56-05:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6b7798d5-571e-4d67-879e-18b2b993c20f'	System	02 May 2021 12:20:58
User entered '02 May 2021 07:20:56'	System	02 May 2021 12:20:58

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:13:18

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:13:18

US3342199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:41

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)	24 Apr 2021 07:50:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-04T12:24:06-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4767df97-ca82-4106-9648-6b9bf02f6867'	System	04 Mar 2021 18:24:17
User entered 'No (N)'	System	04 Mar 2021 18:24:17

US3342199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:50:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2021-03-04T12:24:10-06:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4767df97-ca82-4106-9648-6b9bf02f6867' User entered '04 Mar 2021 12:24:10'	System	04 Mar 2021 18:24:17
	System	04 Mar 2021 18:24:17

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:20:54

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:20:54

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:20:54

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:20:54

US3342199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:20:59

US3342199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:52:53
User entered 'I'	System	23 Nov 2020 23:20:59

US3342199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:37:00

US3342199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:37:00

US3342199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:37:00

US3342199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:37:00

US3342199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:37:04

US3342199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'I'	System	28 Dec 2020 21:37:04

US3342199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:15:12

US3342199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:15:12

US3342199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:15:12

US3342199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:15:12

US3342199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:15:15

US3342199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'I'	System	27 Jan 2021 17:15:15

US3342199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:02

US3342199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:02

US3342199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:02

US3342199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:02

US3342199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:21

US3342199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'I'	System	26 Feb 2021 17:38:21

US3342199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:29

US3342199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:29

US3342199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Clinic (Clinic)'	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:29

US3342199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'VISIT4'	System	24 Mar 2021 19:23:29

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '08:31'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered '24 Mar 2021 08:31'	System	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '97.7' F	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered empty.	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '56'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'bpm'	System	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '12'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'breaths/min'	System	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '120'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'mmHg'	System	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '85'	Ethan Shotton (b) (4)	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'mmHg'	System	29 Mar 2021 12:38:20

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28

US3342199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28

US3342199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:45

US3342199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered empty.	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:45

US3342199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Mar 2021 12:34:09

US3342199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	Ethan Shotton (b) (4)	29 Mar 2021 12:34:09

US3342199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '08:52'	Ethan Shotton (b) (4)	29 Mar 2021 12:34:09

US3342199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered '24 Mar 2021 08:52'	System	29 Mar 2021 12:34:09

US3342199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	24 Mar 2021 19:23:38

US3342199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:10:28
User entered 'I'	System	24 Mar 2021 19:23:38

US3342199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:25

US3342199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:28
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:25

US3342199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:25

US3342199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:28
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:25

US3342199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:29

US3342199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 17:43:29

US3342199

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:03:56

US3342199

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	Darrell O'Brien (b) (4)	14 Jan 2021 21:03:56

US3342199

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:03:56

US3342199

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:03:56

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '0'	Ethan Shotton (b) (4)	09 Mar 2021 13:43:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:34

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	09 Mar 2021 13:43:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:34

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 14:12:05
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4) (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:12:05
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41
	(b) (4)	

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '1'	System	14 Jan 2021 21:04:41

US3342199

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	14 Jan 2021 21:04:41

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered empty.	System	14 Jan 2021 21:36:01
DataPoint set to visible.	System	14 Jan 2021 21:04:41

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered empty.	System	14 Jan 2021 21:36:01
DataPoint set to visible.	System	14 Jan 2021 21:04:41

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14:25'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '14 Jan 2021 14:25'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '098.6' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '066'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '012'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '125'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '076'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered empty.	System	14 Jan 2021 21:36:01
DataPoint set to visible.	System	14 Jan 2021 21:04:41

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '15:34'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '14 Jan 2021 15:34'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '098.2' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '060'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '011'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '126'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '080'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:01

US3342199

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	14 Jan 2021 21:36:01

US3342199

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:56

US3342199

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	Darrell O'Brien (b) (4)	14 Jan 2021 21:04:56

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mRNA-1273'	System	14 Jan 2021 21:44:37
DataPoint set to visible.	System	14 Jan 2021 21:04:41

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered '15:03'	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '14 Jan 2021 15:03'	System	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:48:35
User entered 'ONCE'	System	14 Jan 2021 21:44:37

US3342199

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 21:44:37

US3342199

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	15 Jan 2021 22:19:14

US3342199

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'sample was received, req number 1F604706909' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:32:31
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	08 Feb 2021 17:58:23
User entered '14 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 18:39:10
	Eileen Euperio (b) (4) (b) (4)	15 Jan 2021 22:19:14

US3342199

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14:57'	Eileen Euperio (b) (4)	15 Jan 2021 22:19:14

US3342199

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '14 Jan 2021 14:57'	System	15 Jan 2021 22:19:14

US3342199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	15 Jan 2021 22:19:26

US3342199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Jan 2021'	Eileen Euperio (b) (4)	15 Jan 2021 22:19:26

US3342199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14:59'	Eileen Euperio (b) (4)	15 Jan 2021 22:19:26

US3342199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '14 Jan 2021 14:59'	System	15 Jan 2021 22:19:26

US3342199

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

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	14 Jan 2021 21:05:02

US3342199

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

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	14 Jan 2021 21:05:02

US3342199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:06:17

US3342199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:27:11
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'can confirm call out of window, protocol deviation logged' (Site from System).	Olivia Hapanowicz (b) (4) (b) (4)	11 Mar 2021 18:47:01
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:20:51
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 16:06:17

US3342199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:06:17

US3342199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 16:06:17

US3342199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:06:20

US3342199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	26 Jan 2021 16:06:20

US3342199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '1'	System	26 Jan 2021 16:06:20
DataPoint set to visible.	System	26 Jan 2021 16:06:20

US3342199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:15

US3342199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:31
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 08:49:27
User entered '10 Feb 2021' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:31:42
Signature has been broken.	(b) (4)	
	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:26:50
	(b) (4)	
User entered '09 Feb 2021' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:26:50
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' answered with 'data entered into EDC under unscheduled 10 Feb 2021. sample collected in error, PD logged & coordinator retrained. unable to enter data under OL-D29 folder which is why unscheduled event created.' (Site from DM).	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:01:23
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:19:34
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
User entered '10 Feb 2021'	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:15
	(b) (4)	

US3342199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Clinic (Clinic)'	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:15

US3342199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'OLD29'	System	10 Feb 2021 20:37:15

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:31:42
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:26:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14:08'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '10 Feb 2021 14:08'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '66'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '12'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '142'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '78'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:31:42
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:26:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '15:03'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '10 Feb 2021 15:03'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '64'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '139'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '85'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	10 Feb 2021 21:12:46

US3342199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:20

US3342199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:20

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mRNA-1273'	System	10 Feb 2021 21:13:12
DataPoint set to visible.	System	26 Jan 2021 16:06:20

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:31:42
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Mar 2021 14:31:42
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:26:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14:33'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '10 Feb 2021 14:33'	System	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'ONCE'	System	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 21:13:12

US3342199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:37:27

US3342199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	10 Feb 2021 20:37:27

US3342199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Feb 2021 15:07:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	22 Feb 2021 19:39:28
Query 'Data is required. Please complete.' answered with 'Data entered in error. ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 14:20:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 14:19:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 14:19:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 14:17:11

US3342199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:07:22
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Site closed due to inclement weather. NTF to be made.' (Site from System).	Ethan Shotton (b) (4) (b) (4)	22 Feb 2021 19:39:44
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 19:39:28
User entered '22 Feb 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Feb 2021 19:39:28
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 14:19:55
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Feb 2021 14:19:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 14:19:55
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 14:17:11
User entered '21 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 14:17:11

US3342199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	22 Feb 2021 19:39:28
reason for change: Data Entry Error	Ethan Shotton (b) (4)	22 Feb 2021 19:39:28
User entered empty; reason for change Data Entry Error	(b) (4)	22 Feb 2021 14:19:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 14:17:11

US3342199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:17:11

US3342199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Feb 2021 19:39:47

US3342199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	22 Feb 2021 19:39:47

US3342199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	24 Mar 2021 19:20:01

US3342199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	Morgan Schulle (b) (4)	24 Mar 2021 19:20:01

US3342199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	24 Mar 2021 19:20:01

US3342199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'OLD57'	System	24 Mar 2021 19:20:01

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Mar 2021 19:22:56
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Mar 2021 19:22:56
User entered '08:31' reason for change: Data Entry Error	Morgan Schulle (b) (4)	24 Mar 2021 19:22:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Mar 2021 19:22:48
User entered empty.	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48
	(b) (4)	

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '24 Mar 2021 08:31'	System	24 Mar 2021 19:22:56
User entered empty.	System	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '97.7' F	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Oral (Oral)'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered empty.	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '56'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '12'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '120'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '85'	Morgan Schulle (b) (4)	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	24 Mar 2021 19:22:48

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35

US3342199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35

US3342199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'No (N)'	Morgan Schulle (b) (4)	24 Mar 2021 19:23:06

US3342199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered empty.	Morgan Schulle (b) (4)	24 Mar 2021 19:23:06

US3342199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Mar 2021 12:33:43

US3342199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '24 Mar 2021'	Ethan Shotton (b) (4)	29 Mar 2021 12:33:43

US3342199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '08:52'	Ethan Shotton (b) (4)	29 Mar 2021 12:33:43

US3342199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '24 Mar 2021 08:52'	System	29 Mar 2021 12:33:43

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:10:41

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:31:24
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:25:48
User entered '10 Feb 2021'	(b) (4)	
	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:24
	(b) (4)	

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:10:41

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '0'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:24

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:10:41

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '0'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:24

US3342199

Folder: **Unscheduled 10 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:10:41**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'I'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:24

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:10:41

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '0'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:24

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered 'Yes (Y)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	29 Mar 2021 14:00:39

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Mar 2021 14:31:33
User entered '10 Feb 2021' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:31:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:31:24
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:26:16
User entered '09 Feb 2021' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:26:16
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 14:25:48
User entered '10 Feb 2021'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:39

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
User entered '14:25'	Olivia Hapanowicz (b) (4)	29 Mar 2021 14:00:39

US3342199

Folder: Unscheduled 10 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:22
User entered '10 Feb 2021 14:25'	System	29 Mar 2021 14:31:33
User entered '09 Feb 2021 14:25'	System	29 Mar 2021 14:26:16
User entered '10 Feb 2021 14:25'	System	29 Mar 2021 14:00:39

US3342199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:10:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:37:48
User closed query 'As per ePro- The eDiary system closes at noon the next day ; after which entries for that day cannot be made. Any verbally reported events that could not be entered should be documented as unsolicited AEs. ' (Site from CRA). Query 'As per ePro- The eDiary system closes at noon the next day ; after which entries for that day cannot be made. Any verbally reported events that could not be entered should be documented as unsolicited AEs. ' answered with 'please specify where in the protocol and CCGs it states this' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:18:41
User opened query 'As per ePro- The eDiary system closes at noon the next day ; after which entries for that day cannot be made. Any verbally reported events that could not be entered should be documented as unsolicited AEs. ' (Site from CRA).	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 14:07:13
User closed query 'Per previous query the subject didn't enter the Headache into the diary so it must be added as an AE so that it is appropriately collected. Please reconcile and complete.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:48:19
Query 'Per previous query the subject didn't enter the Headache into the diary so it must be added as an AE so that it is appropriately collected. Please reconcile and complete.' answered with 'this is a solicited adverse reaction. pt did not report on ed diary in error. does not meet AE reporting criteria.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:48:19
User opened query 'Per previous query the subject didn't enter the Headache into the diary so it must be added as an AE so that it is appropriately collected. Please reconcile and complete.' (Site from CRA).	Olivia Hapanowicz (b) (4) (b) (4)	11 Feb 2021 16:52:09
User closed query 'Re-query x2: Per review of AE log Headache is still not entered. Please reconcile and enter since subject didn't record in diary.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:31:58
	(b) (4), (b) (6)	29 Dec 2020 02:31:58

US3342199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:10:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Re-query x2: Per review of AE log Headache is still not entered. Please reconcile and enter since subject didn't record in diary.' answered with 'HA did not last beyond Day 7 ' (Site from CRA).	Eileen Euperio (b) (4)	23 Nov 2020 13:59:15
User opened query 'Re-query x2: Per review of AE log Headache is still not entered. Please reconcile and enter since subject didn't record in diary.' (Site from CRA).	(b) (4)	
User closed query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:09:17
Query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' answered with 'AE entered in AE log' (Site from CRA).	Stefanie Mott (b) (4)	18 Nov 2020 15:41:51
User opened query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:48:02
User closed query 'Please add AE of headache noted on conmed source (06SEP2020).' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:48:02
Query 'Please add AE of headache noted on conmed source (06SEP2020).' answered with 'per source, headache is a solicited AR that was not entered in ed diary by subject in error' (Site from CRA).	Eileen Euperio (b) (4)	02 Oct 2020 18:42:30
User opened query 'Please add AE of headache noted on conmed source (06SEP2020).' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:08:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:31:01
	Eileen Euperio (b) (4)	18 Sep 2020 19:25:18
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:06
Un-reviewed for Safety.		01 Oct 2020 12:09:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:57:09
User entered 'USA-US203-2020-mRNA-1273-P301000002'	System	20 Sep 2020 17:57:05
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:57:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 05:15:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:13:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:13:29
Data point term sent to Coder	System	09 Oct 2020 20:24:44
Coding entries removed.	Eileen Euperio (b) (4)	09 Oct 2020 20:24:16
	(b) (4)	
User entered 'ACUTE FOCAL COLITIS' reason for change: New Information	Eileen Euperio (b) (4)	09 Oct 2020 20:24:16
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 20:55:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 20:55:54
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:54:25
DataPoint Un-verified.	Morgan Schulle (b) (4)	01 Oct 2020 20:54:11
	(b) (4)	
Coding entries removed.	Morgan Schulle (b) (4)	01 Oct 2020 20:54:11
	(b) (4)	
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	Morgan Schulle (b) (4)	01 Oct 2020 20:54:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 05:15:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 05:15:48
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:43:04
User entered 'colitis-unspecified'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	28 Sep 2020 23:29:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:48:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety).	Eileen Euperio (b) (4)	28 Sep 2020 23:29:35
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:29
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:52:17
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:18
Query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:35:35
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:35:30
User opened query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:54:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:42:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:21
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:05
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'I'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '15 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'None (NONE)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'I'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:35:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:29
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:52:36
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:42:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Eileen Euperio (b) (4)	18 Sep 2020 19:42:34
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:05
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

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Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:30:24
User closed query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were 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)	19 Nov 2020 21:01:53
Query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added labs and CT to conproc. CRF' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:48:41
User opened query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were 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)	11 Nov 2020 10:37:44
User closed query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:15:51
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)	12 Oct 2020 14:15:48
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)	12 Oct 2020 14:15:43
Query 'PV Query: Please provide results of stool cultures, if done.' answered with 'stool cultures not documented in med records' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:09:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[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 'updated narrative' (Site from Safety).	Eileen Euperio (b) (4)	09 Oct 2020 20:08:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated narrative' (Site from Safety).	Eileen Euperio (b) (4)	09 Oct 2020 20:08:27
DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:08:11
User entered 'SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020.SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020. CT of abdomen/pelvic showed 3cm segment of circumferential bowel wall thickening in the sigmoid colon with significant periserosal inflammatory changes along its mesenteric side, worrisome for malignancy. Diagnostic considerations also include focal colitis. CBC labs show elevated WBC at 14.4 thou/cu mm on day of admittance 9/13/2020, back to normal values of 9.3 and 7.4 thou/cu mm on 9/14/2020 and 9/15/2020 respectively. RBC levels low at 4.05, 3.75 and 3.52 mlll/cu mm; Hgb 13.4, 12.4, 11.8 g/dL, Hct 38.3, 36.0, 34.6 percent, MCV high at 94.6, 96.0, 98.3 fL, MCH high at 33.1, 33.1, 33.5 pg, on 9/13/2020, 9/14/2020, and 9/15/2020. Differential panel show high neutro auto 76.8 and 69.8 percent, and lymph auto low at 13.5 and 18.7 percent, on 9/13/2020 and 9/15/2020. UA all in normal range on 9/13/2020. Routine chemistry showed high glucose on 9/13/2020 at 118mg/dL. Glucose levels were 98 and 92 mg/dL on 9/14/2020 and 9/15/2020. SARSCOV2 testing done on /13/2020, target nucleic acids not detected.' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Oct 2020 20:08:11

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 17:06:37
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)	07 Oct 2020 17:06:30
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)	07 Oct 2020 17:06:21
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:55
User closed query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:51
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)	01 Oct 2020 12:08:43
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)	01 Oct 2020 12:08:37
Query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' answered with 'per PI, no risk factors present based on patient's current med hx' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:54:15
Query 'PV Query: Please provide results of stool cultures, if done.' answered with 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:36:11
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 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:36:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:35:51
User opened query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:55:09
User opened query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:54:29
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)	28 Sep 2020 15:52:56
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)	28 Sep 2020 15:51:54
User entered 'Subject went to hospital on 13Sep2020 for abdominal pain and fever. Admitted, CT scan done, Dx Colitis. Given antibiotics. Released from hospital on 15Sep2020.'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:42:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 14:19:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 14:19:39
User closed query 'Per MM, to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "lymphadenopathy ipsilateral to injection site".' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:24:57
User closed query 'Per MM: Please update to reflect the location, if known. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:24:54
User closed query 'Per DM CLR: PLease provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:22:43
Data point term sent to Coder	System	16 Mar 2021 13:38:49
Query 'Per MM, to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "lymphadenopathy ipsilateral to injection site".' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:38:30
Query 'Per MM: Please update to reflect the location, if known. ' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:38:27
Query 'Per DM CLR: PLease provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:38:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:38:16
User entered 'LYMPHADENOPATHY R side contralateral to injection site in R axillae' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:38:16
User opened query 'Per MM, to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "lymphadenopathy ipsilateral to injection site".' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:43:56
User opened query 'Per MM: Please update to reflect the location, if known. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:43:40
User opened query 'Per DM CLR: PLease provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:23:44
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:04:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:04:06
Data point term sent to Coder	System	22 Feb 2021 20:02:49
User entered 'Lymphadenopathy'	Ethan Shotton (b) (4) (b) (4)	22 Feb 2021 20:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '10 Feb 2021'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '19:00'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User entered '10 Feb 2021 19:00'	System	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '11 Feb 2021'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '07:00'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User entered '11 Feb 2021 07:00'	System	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Related (RELATED)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'I'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[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 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Ethan Shotton (b) (4)	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User entered '0'	System	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04
User entered '0'	System	22 Feb 2021 20:02:16

US3342199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 18:38:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 18:38:41
Data point term sent to Coder	System	08 Mar 2021 15:14:58
User entered 'acute focal colitis #2'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '07 Mar 2021'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User entered empty.	System	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)' reason for change: New Information	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:44
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '15 Mar 2021' reason for change: New Information	(b) (4)	16 Mar 2021 13:37:44
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User entered empty.	System	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0' reason for change: New Information	(b) (4) Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:44
User entered '1'	(b) (4) Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '1' reason for change: New Information	(b) (4)	
	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:44
User entered '0'	(b) (4)	
	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[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 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User entered '0'	System	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11
User entered 'I'	System	08 Mar 2021 15:14:41

US3342199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:11

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:35
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 19:58:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 19:58:39
Comment added 'does not meet AE reporting criteria according to protocol & eCRF guidelines, but per query resolution, written as AE.'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:58:38
Data point term sent to Coder	System	19 Mar 2021 19:58:02
User entered 'headache'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:33
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:31
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:30
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:29
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '06 Sep 2020'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:27
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
User entered empty.	System	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '06 Sep 2020'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:18
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
User entered empty.	System	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:15
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:10
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:08
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:06
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:02
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:01
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:59
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:57
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:54
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Related (RELATED)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:51
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:49
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'None (NONE)'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:46
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:44
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'l'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:37
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered '0'	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[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 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:36
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:36
User entered empty.	Olivia Hapanowicz (b) (4)	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
User entered '0'	System	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13
User entered '0'	System	19 Mar 2021 19:57:48

US3342199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:02:13

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User closed query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:48:28
Query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' answered with 'data entered' (Site from CRA).	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:53:54
User opened query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:37:17
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:31:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:10:07

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:53:55
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 Sep 2020 20:53:55
Data point term sent to Coder	System	04 Sep 2020 20:34:59
User entered 'acyclovir'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'herpes simplex virus type 1'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '400'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '24 Aug 2015'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:45:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:45:48
Data point term sent to Coder	System	04 Sep 2020 20:44:26
User entered 'pseudoephedrine'	(b) (4), (b) (6) 	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'seasonal allergies'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '60'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Lisa Johnson (b) (4)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'un UNK 1985'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:05:48
Data point term sent to Coder	System	09 Oct 2020 20:29:55
Coding entries removed.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 06:40:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 06:40:46
Data point term sent to Coder	System	18 Sep 2020 19:48:21
User entered 'metronidazole'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:27
User entered 'AE ACUTE FOCAL COLITIS' reason for change: New Information	(b) (4) Eileen Euperio (b) (4)	09 Oct 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'AE colitis'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '500'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
DataPoint Un-verified.	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4) Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
DataPoint Un-verified.	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
User entered '20 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	18 Sep 2020 19:48:07
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User entered '3'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User entered '1'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:34
User entered '804 (804)'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 23:06:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 23:06:25
Data point term sent to Coder	System	09 Oct 2020 20:29:55
Coding entries removed.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 05:13:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 05:13:47
Data point term sent to Coder	System	18 Sep 2020 19:49:26
User entered 'ciprofloxacin'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:34
User entered 'AE ACUTE FOCAL COLITIS' reason for change: Data Entry Error	(b) (4) Eileen Euperio (b) (4)	09 Oct 2020 20:29:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'AE colitis'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '500'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'twice daily (BID)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	18 Sep 2020 19:49:12
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	18 Sep 2020 19:48:53
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:49:12
User entered '13'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	28 Sep 2020 23:29:57
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '24 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:57
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User entered '2'	System	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User entered '1'	System	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:43
User entered '804 (804)'	System	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
Data point term sent to Coder	System	01 Oct 2020 20:56:29
User entered 'NAPROXEN'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:09:22
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' answered with 'this is a solicited adverse reaction. pt did not report on edairy in error. does not meet AE reporting criteria.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	11 Feb 2021 16:51:24
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:45:37
User entered 'HEADACHE'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '220'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once (ONCE)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '06 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Morgan Schulle (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '06 Sep 2020'	Morgan Schulle (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User entered empty.	System	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User entered empty.	System	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:50
User entered empty.	System	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:42:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:42:33
Data point term sent to Coder	System	09 Oct 2020 20:26:47
User entered 'ACETAMINOPHEN-CODEINE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '300/30'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:58:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	10 Feb 2021 20:35:43
User entered 'No (N)' reason for change: New Information	Olivia Hapanowicz (b) (4) (b) (4)	10 Feb 2021 20:35:35
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:47:18
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '25 Sep 2020' reason for change: New Information	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:35:35
User entered empty.	Eileen Euperio (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User entered empty.	System	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User entered empty.	System	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:55
User entered empty.	System	09 Oct 2020 20:26:32

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:26
Data point term sent to Coder	System	09 Oct 2020 20:27:47
User entered 'ZOLPIDEM'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'INSOMNIA'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '5'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UN UNK 2018'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:18
Data point term sent to Coder	System	09 Oct 2020 20:28:52
User entered 'CEFTRIAXONE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:31:42
Query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' answered with 'done' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	29 Oct 2020 19:41:25
User entered 'UNK' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	29 Oct 2020 19:41:16
User opened query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:10:04
User entered 'UN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Other (OTHER)'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Intramuscular (INTRAMUSCULAR)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '14 Sep 2020'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '14 Sep 2020'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User entered empty.	System	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User entered empty.	System	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:04
User entered empty.	System	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
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: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:28
Data point term sent to Coder	System	09 Oct 2020 20:28:52
User entered 'PIPERACILLIN/TAZOBACTAM'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:45:07
Query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' answered with 'Updated to unknown.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 16:22:11
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:22:00
User opened query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:11:28
User entered 'UN'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Intravenous (INTRAVENOUS)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User entered empty.	System	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User entered empty.	System	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:11
User entered empty.	System	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
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) (b) (4)	10 Oct 2020 04:02:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:02:23
Data point term sent to Coder	System	09 Oct 2020 20:29:53
User entered 'FAMOTIDINE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:45:14
Query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' answered with 'Updated to unknown.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 16:22:45
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:22:33
User opened query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK'.Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:11:45
User entered 'UN'	Eileen Euperio (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:59:39
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:36:07
User entered 'No (N)' reason for change: New Information	Olivia Hapanowicz (b) (4)	10 Feb 2021 20:36:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:47:41
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '25 Sep 2020' reason for change: New Information	Olivia Hapanowicz (b) (4) (b) (4)	10 Feb 2021 20:36:03
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User entered empty.	System	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User entered empty.	System	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:16
User entered empty.	System	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:45:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:45:23
Data point term sent to Coder	System	09 Oct 2020 20:31:56
User entered 'ALLOPURINOL'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'MAINTAINENCE DRUG FOR POST PARTIAL NEPHRECTOMY'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '100'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once daily (QD)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UN Sep 2019'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'UN Feb 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User entered '1'	System	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User entered '1'	System	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:23
User entered '804 (804)'	System	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
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) (b) (4)	24 Oct 2020 05:46:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:46:23
Data point term sent to Coder	System	23 Oct 2020 16:00:59
User entered 'Yearly Flu Vaccine'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Yearly Flu Prevention'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '.5'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mL (mL)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '16 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '16 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User entered empty.	System	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User entered empty.	System	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:21
User entered empty.	System	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 21:54:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 21:54:28
Data point term sent to Coder	System	28 Dec 2020 21:53:23
User entered 'Shingles Vaccine'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'shingles prophylaxis'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'l'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'injection'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '9 Nov 2020'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '9 Nov 2020'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User entered empty.	System	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User entered empty.	System	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:26
User entered empty.	System	28 Dec 2020 21:52:31

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:57:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:57:40
Data point term sent to Coder	System	16 Mar 2021 13:36:47
User entered 'ciprofloxacin'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'acute focal colitis #2 AE'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '500'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	24 Mar 2021 19:14:29
Signature has been broken.	(b) (4)	
	Morgan Schulle (b) (4)	24 Mar 2021 19:14:29
User entered 'twice daily (BID)' reason for change:	Morgan Schulle (b) (4)	24 Mar 2021 19:14:29
Data Entry Error	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'once daily (QD)'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:36:15
	(b) (4)	

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '08 Mar 2021'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '15 Mar 2021'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User entered '2'	System	24 Mar 2021 19:14:29
User entered '1'	System	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User entered '1'	System	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:41
User entered '804 (804)'	System	16 Mar 2021 13:36:15

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:13:43
Data point term sent to Coder	System	16 Mar 2021 13:37:48
User entered 'metronidazole'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'acute focal colitis #2 AE'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '500'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'mg (mg)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:50
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	24 Mar 2021 19:14:46
Signature has been broken.	(b) (4)	
	Morgan Schulle (b) (4)	24 Mar 2021 19:14:46
User entered 'three times daily (TID)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	24 Mar 2021 19:14:46
User signature succeeded.	(b) (4)	
	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'twice daily (BID)'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:01
	(b) (4)	

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'Oral (ORAL)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '08 Mar 2021'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered '15 Mar 2021'	Olivia Hapanowicz (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:49:57
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User entered '3'	System	24 Mar 2021 19:14:46
User entered '2'	System	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User entered '1'	System	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:34
User entered '804 (804)'	System	16 Mar 2021 13:37:01

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:10:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	18 Nov 2020 19:31:28

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Nov 2020 19:47:20
	(b) (4)	

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'CT scan abdomen/pelvis'	(b) (4) Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:41

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 20:08:44
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Nov 2020 19:47:33
	(b) (4)	

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'CBC labs'	Eileen Euperio (b) (4)	18 Nov 2020 19:47:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4)	18 Nov 2020 19:47:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 19:47:33
	(b) (4)	

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:42
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Nov 2020 19:48:17

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:42
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'CBC LABS' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 20:07:50
User entered 'routine chemistry labs'	Eileen Euperio (b) (4)	18 Nov 2020 19:48:17
	(b) (4)	

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:42
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4)	18 Nov 2020 19:48:17

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:42
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 19:48:17

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:44
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '15 Sep 2020'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:39

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:44
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'routine chemistry'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:39

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:44
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:39

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:41

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:44
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:13:39

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:47
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '14 Sep 2020'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:47
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'ROUTINE CHEMISTRY'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:47
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:47
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	Eileen Euperio (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:48
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '13 Sep 2020'	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:14:07
	(b) (4)	

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:48
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'ROUTINE CHEMISTRY'	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:14:07

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:48
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4)	18 Nov 2020 20:14:07

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:48
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:14:07

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered '25 Sep 2020'	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:17:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered 'COLONOSCOPY'	Eileen Euperio (b) (4)	18 Nov 2020 20:17:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 05:57:33
' canceled (Site from DM).		
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.	(b) (4), (b) (6)	05 Mar 2021 06:55:51
' (Site from DM).		
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:17:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:50
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
User entered empty.	(b) (4) Eileen Euperio (b) (4)	18 Nov 2020 20:17:33

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	Brett Hubbard (b) (4)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	Brett Hubbard (b) (4)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4) (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '20/Sep/2020 14:32'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:41

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '29/Sep/2020 10:49'	System	29 Sep 2020 14:49:32

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:41

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
User entered 'I'		29 Sep 2020 14:49:32

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4) (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '01/Oct/2020 08:09'	System	01 Oct 2020 12:09:27

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:41

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 12:31:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 12:09:27

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:40:28
User entered '02/Oct/2020 12:31'	System	02 Oct 2020 12:31:25

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:41

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:40:28
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:17:12
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:31:25

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30
	(b) (4)	

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:40:28
User entered '12/Oct/2020 14:17'	System	12 Oct 2020 14:17:25

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:41

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:40:28
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:17:25