

US3542199 (Prod: George Washington University)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3542199

Form: Participant Creation

Data signed: (b) (4) 14 Sep 2020 05:10:25

Generated On: 10 Jun 2021 08:09:08

Participant ID

US3542199

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

US3542199

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3542199

Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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

US3542199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Sep 2020 05:10:26

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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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Condition	HYPERTROPHIC CARDIOMYOPATHY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Oct 2020 18:49:34

Generated On: 10 Jun 2021 08:09:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:36
Height (xxx.x)	66.5 in
Weight (xxx.x)	159 lb
BMI (xxx.x)	25.33166 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 17 Sep 2020 04:31:31

Generated On: 10 Jun 2021 08:09:08

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) 17 Sep 2020 04:31:31

Generated On: 10 Jun 2021 08:09:08

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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 21 Oct 2020 18:49:34

Generated On: 10 Jun 2021 08:09:08

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190365

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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:36
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)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:42
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 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 19:34:48

Generated On: 10 Jun 2021 08:09:08

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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 11:12

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) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

10 SEP 2020 09:55

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:58	10 SEP 2020 09:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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: 10 Jun 2021 08:09:08

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

10 SEP 2020 11:32

PC Open Date & Time

10 SEP 2020 11:32

PC Close Date & Time

10 SEP 2020 14:02

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 98.8 °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	10 SEP 2020 20:15
PC Open Date & Time	10 SEP 2020 14:57
PC Close Date & Time	11 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 20:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 17:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

14 SEP 2020 20:26

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:38

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 11:33

PC Open Date & Time

10 SEP 2020 11:32

PC Close Date & Time

10 SEP 2020 14:02

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

10 SEP 2020 20:16

PC Open Date & Time

10 SEP 2020 14:57

PC Close Date & Time

11 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

11 SEP 2020 20:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

12 SEP 2020 17:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

13 SEP 2020 19:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

14 SEP 2020 20:27

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

15 SEP 2020 22:38

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

16 SEP 2020 23:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 11:33
PC Open Date & Time	10 SEP 2020 11:32
PC Close Date & Time	10 SEP 2020 14:02

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:17
PC Open Date & Time	10 SEP 2020 14:57
PC Close Date & Time	11 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:53
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:26
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:07
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

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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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:27
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 ☒

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EAB) (1725)

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:39
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

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EAB) (1725)

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 23:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3542199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Sep 2020 11:55:13

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Sep 2020 11:55:13

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Sep 2020 04:35:32

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:35:32

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 04:22:40

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

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)	08 OCT 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 08:30
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

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)	08 OCT 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 09:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	44 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Oct 2020 04:22:40

Generated On: 10 Jun 2021 08:09:08

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 09:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3542199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 OCT 2020
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	08 OCT 2020 08:35

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:34:48

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)			08 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:38	08 OCT 2020 08:38
Nasopharyngeal Swab 2	No		

US3542199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 04:22:40

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 09:46

PC Open Date & Time

08 OCT 2020 09:35

PC Close Date & Time

08 OCT 2020 12:05

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	08 OCT 2020 17:54
PC Open Date & Time	08 OCT 2020 13:00
PC Close Date & Time	09 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

97.8 °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 OCT 2020 20:50

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 21:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

97.1 °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

12 OCT 2020 09:31

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 19:42

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:24

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 20:48

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 09:46

PC Open Date & Time

08 OCT 2020 09:35

PC Close Date & Time

08 OCT 2020 12:05

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

08 OCT 2020 17:55

PC Open Date & Time

08 OCT 2020 13:00

PC Close Date & Time

09 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

09 OCT 2020 20:50

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

10 OCT 2020 21:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

12 OCT 2020 09:32

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

12 OCT 2020 19:42

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

13 OCT 2020 21:24

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	14 OCT 2020 20:47
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 09:47
PC Open Date & Time	08 OCT 2020 09:35
PC Close Date & Time	08 OCT 2020 12:05

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 17:56
PC Open Date & Time	08 OCT 2020 13:00
PC Close Date & Time	09 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 20:51
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 21:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 09:32
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

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EAB) (1725)

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 19:43
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

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EAB) (1725)

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:24
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

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EAB) (1725)

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 20:47
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3542199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 18:49:34

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:49:34

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 01:42:07

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:42:07

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:42
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)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

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.

US3542199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 NOV 2020
Collection time (00:00-23:59)	08:49 (24 HR)
Collection date and time (derived)	05 NOV 2020 08:49

US3542199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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	12 NOV 2020 10:11:12
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 10:25:48

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	24 NOV 2020 07:25:42
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 <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	28 NOV 2020 10:19:43
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 10:04:15
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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	14 DEC 2020 10:13:22
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

19 DEC 2020 10:13:39

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 10:13:54
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 10:13:43
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 10:25:46
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

16 JAN 2021 10:15:02

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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	23 JAN 2021 10:14:44
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 JAN 2021 07:01:43
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

09 FEB 2021 17:59:37

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 12:02:30

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 09:02:08
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

28 FEB 2021 10:17:16

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 10:21:55
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 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	15 MAR 2021 12:30:51
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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	20 MAR 2021 11:16:09
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

29 MAR 2021 11:16:39

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

05 APR 2021 15:03:55

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

14 APR 2021 12:04:40

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

17 APR 2021 23:20:46

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

27 APR 2021 18:45:58

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 <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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 <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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

DAY 761

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

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

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

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

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

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

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3542199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:09:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 10:16:59

US3542199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:10:12

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:10:12

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:04:43

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:04:43

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:43:22

Generated On: 10 Jun 2021 08:09:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:43:22

Generated On: 10 Jun 2021 08:09:08

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:43:22

Generated On: 10 Jun 2021 08:09:08

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.

US3542199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:43:22

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	08:45 (24 HR)
Collection date and time (derived)	01 APR 2021 08:45

US3542199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:43:22

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542199

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:09:08

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"/>

US3542199

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:09:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542199

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

Form: Visit Date

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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

Visit date (dd MMM yyyy)	04 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3542199

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:10:53

Generated On: 10 Jun 2021 08:09:08

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 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>)	04 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

US3542199

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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

US3542199

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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)	04 JAN 2021
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 08:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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)	04 JAN 2021
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 09:32
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

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

Form: Physical Examination

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 JAN 2021

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

US3542199

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

Form: Exposure

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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) 04 JAN 2021

What was the treatment time? (00:00-23:59) 09:02 (24 HR)

Treatment Date and Time (derived) 04 JAN 2021 09:02

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

US3542199

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Jan 2021 02:43:45

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00-23:59)	08:58 (24 HR)
Collection date and time (derived)	04 JAN 2021 08:58

US3542199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

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

US3542199

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

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:47:10

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Jan 2021 02:43:45

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Jan 2021 02:43:45

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3542199

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	OLD29

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

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)	29 JAN 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 09:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	46 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

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)	29 JAN 2021
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 09:57
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)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3542199

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JAN 2021

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

US3542199

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 09:20 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 09:20

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

What was the frequency of the study treatment dosing? ONCE

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

US3542199

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 31 Jan 2021 19:22:50

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:04:43

Generated On: 10 Jun 2021 08:09:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:04:43

Generated On: 10 Jun 2021 08:09:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542199

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542199

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

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.

US3542199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 00:42:54

Generated On: 10 Jun 2021 08:09:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 MAR 2021

Collection time (00:00-23:59)

09:06 (24 HR)

Collection date and time (derived)

05 MAR 2021 09:06

US3542199

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 13:52:22

Generated On: 10 Jun 2021 08:09:08

AEID	USA-US084-2021-MRNA-1273-P30 1000007
Adverse event	RENAL CELL CARCINOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	29 OCT 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) 01 Apr 2021 13:52:22

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 13:52:22

Generated On: 10 Jun 2021 08:09:08

RENAL MASS WAS DETECTED
ON AN MRI THAT WAS DONE
TO INVESTIGATE LIVER CYSTS
FOUND ON ROUTINE
ABDOMINAL ULTRASOUND
(16SEP2020) ORDERED BY PCP
TO INVESTIGATE MILDLY
ELEVATED LIVER ENZYMES
(VALUES NOT AVAILABLE).
THE MRI ON 02OCT2020
CONFIRMED BENIGN LIVER
CYSTS BUT INCIDENTALLY
REVEALED A LEFT UPPER POLE
KIDNEY MASS. PARTICIPANT
SUBSEQUENTLY UNDERWENT
A LAPAROSCOPIC PARTIAL
NEPHRECTOMY ON 27OCT2020.
PATHOLOGY SHOWED RENAL
CELL CARCINOMA AND THAT
THE ENTIRE LESION WAS
REMOVED. NO FURTHER
TREATMENT INDICATED.
PARTICIPANT HOSPITALIZED
27OCT2020 THRU 29OCT2020
FOR THE PROCEDURE AND
ASSOCIATED PAIN
MANAGEMENT. HE
RECOVERED WELL AND
WITHOUT INCIDENT OR
COMPLICATIONS.

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

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 14 Sep 2020 05:10:26

Generated On: 10 Jun 2021 08:09:08

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

Yes ☒

No ☐

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

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication CARDIOMYOPATHY

Dose per administration 25

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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US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CARDIOMYOPATHY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CARDIOMYOPATHY

Dose per administration 81

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 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 (4)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 25

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication FEXAFENIDINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication AZELASTINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 137

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (7)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication OLOPADINE 0.01%

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		OPHTHALMIC
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 OCT 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"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	29 OCT 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"/>	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 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"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CARDIOMYOPATHY

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication FLUAD

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)		22 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)		22 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"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication LEFT PARTIAL NEPHRECTOMY

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication DOCUSATE

Prophylaxis Yes ☐
No ☒

Indication LEFT 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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"/>

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

Name of Medication ZOFRAN (ONDANSETRON)

Prophylaxis Yes ☐
No ☒

Indication LEFT PARTIAL NEPHRECTOMY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Mar 2021 18:09:28

Generated On: 10 Jun 2021 08:09:08

	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)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Nov 2020 22:01:57

Generated On: 10 Jun 2021 08:09:08

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 10 Mar 2021 18:41:17

Generated On: 10 Jun 2021 08:09:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	LEFT PARTIAL NEPHRECTOMY	Adverse Event	
27 OCT 2020	LEFT URETERAL CATHETER PLACEMENT	Adverse Event	

US3542199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:08

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

US3542199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:09:08

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 ☐

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/MAR/2021 15:23
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

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 11:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/MAR/2021 08:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:50
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

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 06:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 16:54:16

Generated On: 10 Jun 2021 08:09:08

SAEID	USA-US084-2021-MRNA-1273-P301000007
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/APR/2021 10:42
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

US3542199 (Prod: George Washington University)

US3542199

Form: Participant Creation

Generated On: 10 Jun 2021 08:09:08

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:00:51
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'US3542199'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:29:54

US3542199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:33

US3542199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:29:55

US3542199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Clinic (Clinic)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:33

US3542199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'SCRN'	System	10 Sep 2020 14:09:33

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:29:56

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '66'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'YEARS'	System	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '66'	System	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Male (M)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59
	(b) (4)	

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:59

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'Sep 2020'	System	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '2020'	System	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Amendment 3 (3)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:44

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:29:55

US3542199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'l'	System	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:09:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:05:37

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Hypertrophic cardiomyopathy, LLT: Hypertrophic cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:10:39
Data point term sent to Coder	System	11 Sep 2020 17:09:52
User entered 'hypertrophic cardiomyopathy'	Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2004'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'Jan 2004'	System	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '2004'	System	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered empty.	System	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered empty.	System	11 Sep 2020 17:09:08

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
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)	11 Sep 2020 17:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:10:39
Data point term sent to Coder	System	11 Sep 2020 17:09:54
User entered 'seasonal allergies'	Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 1960'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'Jan 1960'	System	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '1960'	System	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered empty.	System	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered empty.	System	11 Sep 2020 17:09:20

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '09:36'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '10 Sep 2020 09:36'	System	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '66.5' in	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22
DataPoint set to visible.	(b) (4) System	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '159' lb	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22
DataPoint set to visible.	(b) (4) System	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered '25.33166'	System	11 Sep 2020 17:06:22
DataPoint set to visible.	System	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'kg/m2'	System	11 Sep 2020 17:06:22
DataPoint set to visible.	System	10 Sep 2020 14:09:49

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:49:34
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	16 Oct 2020 13:55:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	DeEnna Wedding (b) (4)	16 Oct 2020 13:55:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
	(b) (4)	
User entered 'Oral (Oral)'	Taylor Ladson (b) (4)	11 Sep 2020 17:06:22
	(b) (4)	

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'bpm'	System	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'breaths/min'	System	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'mmHg'	System	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User entered 'mmHg'	System	11 Sep 2020 17:06:22

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50

US3542199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50

US3542199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:49:01
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	11 Feb 2021 20:49:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:06:28

US3542199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:49:01
User entered '10 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	11 Feb 2021 20:49:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:06:28

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

[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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

[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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:07:40
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	14 Sep 2020 17:07:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Sep 2020 17:08:33
	Taylor Ladson (b) (4)	11 Sep 2020 17:08:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:50
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:31:31
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:33

US3542199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4)	10 Sep 2020 15:22:16

US3542199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	10 Sep 2020 15:22:16

US3542199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[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 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered 'Clinic (Clinic)'	(b) (4) Hira Qadir (b) (4) (b) (4)	10 Sep 2020 15:22:16

US3542199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'VISIT1'	System	10 Sep 2020 15:22:16

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:54:26

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '190365'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:54:26

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:54:26

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:45

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:45

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:45

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:45

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:45

US3542199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:49:34
User entered 'No (N)'	(b) (4)	
	DeEnna Wedding (b) (4)	16 Oct 2020 13:55:46
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:56:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:56:16

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '09:36'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '10 Sep 2020 09:36'	System	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '98.7' F	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '51'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'bpm'	System	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '14'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'breaths/min'	System	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '123'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '73'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:09

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '11:42'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '10 Sep 2020 11:42'	System	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '98' F	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '62'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'bpm'	System	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '18'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'breaths/min'	System	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '115'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 05:10:26
User entered '75'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	11 Sep 2020 17:08:14

US3542199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:50:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Feb 2021 20:50:17
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:34

US3542199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:50:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Feb 2021 20:50:17
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:06:34

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Hira Qadir (b) (4)	10 Sep 2020 15:21:56
	(b) (4)	

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Hira Qadir (b) (4)	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Hira Qadir (b) (4)	10 Sep 2020 15:21:56
	(b) (4)	

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	14 Sep 2020 05:10:26
User entered '11:12'	(b) (4) Hira Qadir (b) (4)	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '10 Sep 2020 11:12'	System	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hira Qadir (b) (4) (b) (4)	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'ONCE'	System	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:21:56

US3542199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:21

US3542199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:21

US3542199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '09:55'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:21

US3542199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '10 Sep 2020 09:55'	System	11 Sep 2020 17:07:21

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '09:58'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '10 Sep 2020 09:58'	System	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered empty.	System	11 Sep 2020 17:07:32

US3542199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:07:45

US3542199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'I'	System	11 Sep 2020 17:07:45

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:17', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2b8870f-4a2a-439f-8fd7-507dc79165d1'	System	10 Sep 2020 15:32:37
User entered 'Yes (Y)'	System	10 Sep 2020 15:32:37

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:24', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2b8870f-4a2a-439f-8fd7-507dc79165d1' User entered '98.0'	System	10 Sep 2020 15:32:37
	System	10 Sep 2020 15:32:37

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2b8870f-4a2a-439f-8fd7-507dc79165d1'	System	10 Sep 2020 15:32:37
User entered 'No (N)'	System	10 Sep 2020 15:32:37

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2b8870f-4a2a-439f-8fd7-507dc79165d1' User entered '10 Sep 2020 11:32'	System	10 Sep 2020 15:32:37
	System	10 Sep 2020 15:32:37

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:02'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:15:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '53cd7637-db71-4ca8-b9bd-035c69f221af' User entered 'Yes (Y)'	System	11 Sep 2020 00:15:55
	System	11 Sep 2020 00:15:55

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:15:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '53cd7637-db71-4ca8-b9bd-035c69f221af' User entered '98.8'	System	11 Sep 2020 00:15:55
	System	11 Sep 2020 00:15:55

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:15:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '53cd7637-db71-4ca8-b9bd-035c69f221af' User entered 'No (N)'	System	11 Sep 2020 00:15:55
	System	11 Sep 2020 00:15:55

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:15:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '53cd7637-db71-4ca8-b9bd-035c69f221af' User entered '10 Sep 2020 20:15'	System	11 Sep 2020 00:15:55
	System	11 Sep 2020 00:15:55

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:57'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 2'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:05', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3d6ead6d-c364-44f1-9835-2ce750ae299c' User entered 'Yes (Y)'	System	12 Sep 2020 00:55:52
	System	12 Sep 2020 00:55:52

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3d6ead6d-c364-44f1-9835-2ce750ae299c' User entered '98.7'	System	12 Sep 2020 00:55:52
	System	12 Sep 2020 00:55:52

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:15', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3d6ead6d-c364-44f1-9835-2ce750ae299c'	System	12 Sep 2020 00:55:52
User entered 'No (N)'	System	12 Sep 2020 00:55:52

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3d6ead6d-c364-44f1-9835-2ce750ae299c'	System	12 Sep 2020 00:55:52
User entered '11 Sep 2020 20:52'	System	12 Sep 2020 00:55:52

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 3'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:24:56', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '54f1e8d8-0608-4e84-8a27-b460b4cc7c3c' User entered 'Yes (Y)'	System	12 Sep 2020 21:25:13
	System	12 Sep 2020 21:25:13

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:02', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '54f1e8d8-0608-4e84-8a27-b460b4cc7c3c' User entered '96.9'	System	12 Sep 2020 21:25:13
	System	12 Sep 2020 21:25:13

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:05', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '54f1e8d8-0608-4e84-8a27-b460b4cc7c3c' User entered 'No (N)'	System	12 Sep 2020 21:25:13
	System	12 Sep 2020 21:25:13

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:10', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '54f1e8d8-0608-4e84-8a27-b460b4cc7c3c' User entered '12 Sep 2020 17:25'	System	12 Sep 2020 21:25:13
	System	12 Sep 2020 21:25:13

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 4'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:03', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8a5215c4-2da1-41ec-804c-987b9780f111' User entered 'Yes (Y)'	System	13 Sep 2020 23:06:19
	System	13 Sep 2020 23:06:19

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:08', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8a5215c4-2da1-41ec-804c-987b9780f111' User entered '98.6'	System	13 Sep 2020 23:06:19
	System	13 Sep 2020 23:06:19

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:11', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8a5215c4-2da1-41ec-804c-987b9780f111'	System	13 Sep 2020 23:06:19
User entered 'No (N)'	System	13 Sep 2020 23:06:19

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8a5215c4-2da1-41ec-804c-987b9780f111' User entered '13 Sep 2020 19:06'	System	13 Sep 2020 23:06:19
	System	13 Sep 2020 23:06:19

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 5'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:25:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '79c765dc-ff43-407e-bd62-d489f1a9527c' User entered 'Yes (Y)'	System	15 Sep 2020 00:26:46
	System	15 Sep 2020 00:26:46

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '79c765dc-ff43-407e-bd62-d489f1a9527c' User entered '98.1'	System	15 Sep 2020 00:26:46
	System	15 Sep 2020 00:26:46

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '79c765dc-ff43-407e-bd62-d489f1a9527c'	System	15 Sep 2020 00:26:46
User entered 'No (N)'	System	15 Sep 2020 00:26:46

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '79c765dc-ff43-407e-bd62-d489f1a9527c' User entered '14 Sep 2020 20:26'	System	15 Sep 2020 00:26:46
	System	15 Sep 2020 00:26:46

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 6'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:37:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '91b2bb6c-7eca-4325-8e2b-57ed0ca5efd3' User entered 'Yes (Y)'	System	16 Sep 2020 02:38:21
	System	16 Sep 2020 02:38:21

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:06', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '91b2bb6c-7eca-4325-8e2b-57ed0ca5efd3' User entered '97.4'	System	16 Sep 2020 02:38:21
	System	16 Sep 2020 02:38:21

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:13', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '91b2bb6c-7eca-4325-8e2b-57ed0ca5efd3'	System	16 Sep 2020 02:38:21
User entered 'No (N)'	System	16 Sep 2020 02:38:21

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '91b2bb6c-7eca-4325-8e2b-57ed0ca5efd3' User entered '15 Sep 2020 22:38'	System	16 Sep 2020 02:38:21
	System	16 Sep 2020 02:38:21

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 7'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:08:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '23f57f81-b82c-47b9-bdc2-677ac5b4c04d' User entered 'Yes (Y)'	System	17 Sep 2020 03:09:16
	System	17 Sep 2020 03:09:16

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:08:58', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '23f57f81-b82c-47b9-bdc2-677ac5b4c04d' User entered '97.0'	System	17 Sep 2020 03:09:16
	System	17 Sep 2020 03:09:16

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:07', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '23f57f81-b82c-47b9-bdc2-677ac5b4c04d' User entered 'No (N)'	System	17 Sep 2020 03:09:16
	System	17 Sep 2020 03:09:16

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '23f57f81-b82c-47b9-bdc2-677ac5b4c04d' User entered '16 Sep 2020 23:09'	System	17 Sep 2020 03:09:16
	System	17 Sep 2020 03:09:16

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '330b985c-1895-484e-9a66-d8197f993448'	System	10 Sep 2020 15:33:11
User entered 'None (1)'	System	10 Sep 2020 15:33:11

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '330b985c-1895-484e-9a66-d8197f993448' User entered 'No (N)'	System	10 Sep 2020 15:33:11
	System	10 Sep 2020 15:33:11

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:32:56', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '330b985c-1895-484e-9a66-d8197f993448' User entered 'No (N)'	System	10 Sep 2020 15:33:11
	System	10 Sep 2020 15:33:11

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:01', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '330b985c-1895-484e-9a66-d8197f993448'	System	10 Sep 2020 15:33:11
User entered 'None (1)'	System	10 Sep 2020 15:33:11

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:07', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '330b985c-1895-484e-9a66-d8197f993448' User entered '10 Sep 2020 11:33'	System	10 Sep 2020 15:33:11
	System	10 Sep 2020 15:33:11

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:02'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6f1ffc4a-3dbe-4c7a-ad1b-4f8edcf5ffa5'	System	11 Sep 2020 00:16:31
User entered 'None (1)'	System	11 Sep 2020 00:16:31

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:02', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6f1ffc4a-3dbe-4c7a-ad1b-4f8edcf5ffa5'	System	11 Sep 2020 00:16:31
User entered 'No (N)'	System	11 Sep 2020 00:16:31

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:10', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6f1ffc4a-3dbe-4c7a-ad1b-4f8edcf5ffa5'	System	11 Sep 2020 00:16:31
User entered 'No (N)'	System	11 Sep 2020 00:16:31

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6f1ffc4a-3dbe-4c7a-ad1b-4f8edcf5ffa5'	System	11 Sep 2020 00:16:31
User entered 'None (1)'	System	11 Sep 2020 00:16:31

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:25', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6f1ffc4a-3dbe-4c7a-ad1b-4f8edcf5ffa5'	System	11 Sep 2020 00:16:31
User entered '10 Sep 2020 20:16'	System	11 Sep 2020 00:16:31

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:57'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 2'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9eb9e959-bccc-45cd-b316-6299ffd882ed'	System	12 Sep 2020 00:55:59
User entered 'None (1)'	System	12 Sep 2020 00:55:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9eb9e959-bccc-45cd-b316-6299ffd882ed' User entered 'No (N)'	System	12 Sep 2020 00:55:59
	System	12 Sep 2020 00:55:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9eb9e959-bccc-45cd-b316-6299ffd882ed' User entered 'No (N)'	System	12 Sep 2020 00:55:59
	System	12 Sep 2020 00:55:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9eb9e959-bccc-45cd-b316-6299ffd882ed'	System	12 Sep 2020 00:55:59
User entered 'None (1)'	System	12 Sep 2020 00:55:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:52:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9eb9e959-bccc-45cd-b316-6299ffd882ed' User entered '11 Sep 2020 20:52'	System	12 Sep 2020 00:55:59
	System	12 Sep 2020 00:55:59

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 3'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:15', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '457eea1f-8917-4fe6-a3a8-08c71ae17cb9'	System	12 Sep 2020 21:25:34
User entered 'None (1)'	System	12 Sep 2020 21:25:34

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:17', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '457eea1f-8917-4fe6-a3a8-08c71ae17cb9' User entered 'No (N)'	System	12 Sep 2020 21:25:34
	System	12 Sep 2020 21:25:34

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '457eea1f-8917-4fe6-a3a8-08c71ae17cb9' User entered 'No (N)'	System	12 Sep 2020 21:25:34
	System	12 Sep 2020 21:25:34

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:25', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '457eea1f-8917-4fe6-a3a8-08c71ae17cb9'	System	12 Sep 2020 21:25:34
User entered 'None (1)'	System	12 Sep 2020 21:25:34

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '457eea1f-8917-4fe6-a3a8-08c71ae17cb9'	System	12 Sep 2020 21:25:34
User entered '12 Sep 2020 17:25'	System	12 Sep 2020 21:25:34

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 4'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bacb4395-2f79-4c67-a489-928cc97f03f3'	System	13 Sep 2020 23:06:40
User entered 'None (1)'	System	13 Sep 2020 23:06:40

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:23', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bacb4395-2f79-4c67-a489-928cc97f03f3'	System	13 Sep 2020 23:06:40
User entered 'No (N)'	System	13 Sep 2020 23:06:40

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bacb4395-2f79-4c67-a489-928cc97f03f3'	System	13 Sep 2020 23:06:40
User entered 'No (N)'	System	13 Sep 2020 23:06:40

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bacb4395-2f79-4c67-a489-928cc97f03f3'	System	13 Sep 2020 23:06:40
User entered 'None (1)'	System	13 Sep 2020 23:06:40

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bacb4395-2f79-4c67-a489-928cc97f03f3'	System	13 Sep 2020 23:06:40
User entered '13 Sep 2020 19:06'	System	13 Sep 2020 23:06:40

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 5'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'ba636da2-8aea-414d-ac65-586a2c05023b' User entered 'None (1)'	System	15 Sep 2020 00:27:08
	System	15 Sep 2020 00:27:08

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:52', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'ba636da2-8aea-414d-ae65-586a2c05023b' User entered 'No (N)'	System	15 Sep 2020 00:27:08
	System	15 Sep 2020 00:27:08

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'ba636da2-8aea-414d-ae65-586a2c05023b' User entered 'No (N)'	System	15 Sep 2020 00:27:08
	System	15 Sep 2020 00:27:08

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:26:57', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'ba636da2-8aea-414d-ac65-586a2c05023b' User entered 'None (1)'	System	15 Sep 2020 00:27:08
	System	15 Sep 2020 00:27:08

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:03', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'ba636da2-8aea-414d-ae65-586a2c05023b' User entered '14 Sep 2020 20:27'	System	15 Sep 2020 00:27:08
	System	15 Sep 2020 00:27:08

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 6'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:27', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '03c21675-210c-4343-bb45-f3e6205253d3'	System	16 Sep 2020 02:38:53
User entered 'None (1)'	System	16 Sep 2020 02:38:53

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '03c21675-210c-4343-bb45-f3e6205253d3' User entered 'No (N)'	System	16 Sep 2020 02:38:53
	System	16 Sep 2020 02:38:53

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '03c21675-210c-4343-bb45-f3e6205253d3' User entered 'No (N)'	System	16 Sep 2020 02:38:53
	System	16 Sep 2020 02:38:53

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '03c21675-210c-4343-bb45-f3e6205253d3'	System	16 Sep 2020 02:38:53
User entered 'None (1)'	System	16 Sep 2020 02:38:53

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:38:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '03c21675-210c-4343-bb45-f3e6205253d3' User entered '15 Sep 2020 22:38'	System	16 Sep 2020 02:38:53
	System	16 Sep 2020 02:38:53

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 7'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:17', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8be99021-bc9d-4fff-a417-b54636d4ddaf'	System	17 Sep 2020 03:09:45
User entered 'None (1)'	System	17 Sep 2020 03:09:45

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8be99021-bc9d-4fff-a417-b54636d4ddaf' User entered 'No (N)'	System	17 Sep 2020 03:09:45
	System	17 Sep 2020 03:09:45

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:28', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8be99021-bc9d-4fff-a417-b54636d4ddaf' User entered 'No (N)'	System	17 Sep 2020 03:09:45
	System	17 Sep 2020 03:09:45

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8be99021-bc9d-4fff-a417-b54636d4ddaf'	System	17 Sep 2020 03:09:45
User entered 'None (1)'	System	17 Sep 2020 03:09:45

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '8be99021-bc9d-4fff-a417-b54636d4ddaf' User entered '16 Sep 2020 23:09'	System	17 Sep 2020 03:09:45
	System	17 Sep 2020 03:09:45

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:24', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:27', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:33', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'None (0)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered 'No (N)'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T11:33:47', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'c903ca1c-3416-4420-aad8-bbc9f8997161' User entered '10 Sep 2020 11:33'	System	10 Sep 2020 15:33:50
	System	10 Sep 2020 15:33:50

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:02'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:40', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:46', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'None (0)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:16:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered 'No (N)'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-10T20:17:05', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1fdc2251-d0bb-4a7e-b1ef-916269cd4531' User entered '10 Sep 2020 20:17'	System	11 Sep 2020 00:17:07
	System	11 Sep 2020 00:17:07

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Sep 2020 14:57'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 2'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:04', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:33', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'None (0)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered 'No (N)'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-11T20:53:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '56017443-6ee2-4554-8920-345eac382fe1' User entered '11 Sep 2020 20:53'	System	12 Sep 2020 00:56:14
	System	12 Sep 2020 00:56:14

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 3'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'None (0)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'None (0)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'None (0)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96' User entered 'None (0)'	System	12 Sep 2020 21:26:13
	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'None (0)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'None (0)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:25:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered 'No (N)'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-12T17:26:03', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '15ca4f4c-5f3e-4a57-8f7a-e5c6bd624b96'	System	12 Sep 2020 21:26:13
User entered '12 Sep 2020 17:26'	System	12 Sep 2020 21:26:13

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 4'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:40', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:50', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:06:57', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'None (0)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:07:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered 'No (N)'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-13T19:07:09', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50cb19c6-384f-44d6-8eac-1bf15fa5a00a' User entered '13 Sep 2020 19:07'	System	13 Sep 2020 23:07:10
	System	13 Sep 2020 23:07:10

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 5'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:09', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:11', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:14', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:19', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'None (0)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered 'No (N)'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-14T20:27:28', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85f864e4-fc96-4a21-8e87-56be9bf74bdc' User entered '14 Sep 2020 20:27'	System	15 Sep 2020 00:27:30
	System	15 Sep 2020 00:27:30

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 6'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:13', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:22', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:24', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:27', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'None (0)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered 'No (N)'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-15T22:39:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '45da2865-3280-4f60-bf46-e341e2387340' User entered '15 Sep 2020 22:39'	System	16 Sep 2020 02:39:45
	System	16 Sep 2020 02:39:45

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 7'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:47', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:52', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:09:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'None (0)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:10:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered 'No (N)'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-09-16T23:10:17', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '76d0783c-8101-4c9c-a0a6-8eb12693a28b' User entered '16 Sep 2020 23:10'	System	17 Sep 2020 03:10:23
	System	17 Sep 2020 03:10:23

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:21:56

US3542199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:55:13
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 17:39:40

US3542199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:55:13
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 17:39:40

US3542199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 17:39:40

US3542199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:55:13
User entered empty.	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 17:39:40

US3542199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:55:13
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 17:39:30

US3542199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	18 Sep 2020 17:39:30

US3542199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:35:32
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Sep 2020 17:38:03

US3542199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:35:32
User entered '24 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Sep 2020 17:38:03

US3542199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Sep 2020 17:38:03

US3542199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:35:32
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Sep 2020 17:38:03

US3542199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:35:32
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Sep 2020 17:38:10

US3542199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	25 Sep 2020 17:38:10

US3542199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:39:53
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	02 Oct 2020 19:40:48

US3542199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:47:11
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:47:11
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:39:53
User entered '1 Oct 2020'	Madhu Balachandran (b) (4)	02 Oct 2020 19:40:48

US3542199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:39:53
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	02 Oct 2020 19:40:48

US3542199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	03 Oct 2020 15:39:53
User entered empty.	Madhu Balachandran (b) (4)	02 Oct 2020 19:40:48

US3542199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:18:49

US3542199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	08 Oct 2020 13:18:49

US3542199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:44:10

US3542199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:45:41
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:45:41
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '8 Oct 2020'	Erika Faust (b) (4)	09 Oct 2020 15:44:10

US3542199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[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 07:54:01
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:22:41
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:44:10

US3542199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'VISIT2'	System	09 Oct 2020 15:44:10

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:46:04
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:46:04
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:04:03
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '08:30'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '08 Oct 2020 08:30'	System	11 Feb 2021 20:46:04
User entered '8 Oct 2020 08:30'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '97.9' F	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	11 Nov 2020 22:04:03
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '47'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'bpm'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'breaths/min'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '121'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '71'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:46:21
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:46:21
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:04:03
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '09:45'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '08 Oct 2020 09:45'	System	11 Feb 2021 20:46:21
User entered '8 Oct 2020 09:45'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '97.9' F	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:04:03
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:07:31
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:04:03
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS. Not an AE.' (Site from System).	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:03:49
	(b) (4)	
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	09 Oct 2020 15:47:07
User entered '44'	Erika Faust (b) (4)	09 Oct 2020 15:47:07
	(b) (4)	

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'bpm'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'breaths/min'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '111'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	11 Nov 2020 22:04:03
User entered '66'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	09 Oct 2020 15:47:07

US3542199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:44:19

US3542199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:46:28
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:46:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:44:19

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered empty.	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered empty.	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '08 Oct 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:22:41
User entered '09:15'	(b) (4) Hira Qadir (b) (4)	08 Oct 2020 13:19:38
	(b) (4)	

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '08 Oct 2020 09:15'	System	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hira Qadir (b) (4) (b) (4)	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'ONCE'	System	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 13:19:38

US3542199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:32

US3542199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:46:40
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:46:40
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:32

US3542199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '08:35'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:32

US3542199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '08 Oct 2020 08:35'	System	11 Feb 2021 20:46:40
User entered '8 Oct 2020 08:35'	System	09 Oct 2020 15:45:32

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:34:48
Signature has been broken.	(b) (4), (b) (6)	11 Feb 2021 20:46:47
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:46:47
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered '8 Oct 2020'	Erika Faust (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:22:41
User entered '08:38'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '08 Oct 2020 08:38'	System	11 Feb 2021 20:46:47
User entered '8 Oct 2020 08:38'	System	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered empty.	System	09 Oct 2020 15:45:57

US3542199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:46:02

US3542199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'I'	System	09 Oct 2020 15:46:02

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:45:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'db082b9d-5f01-419e-a342-4d957afc3e71' User entered 'Yes (Y)'	System	08 Oct 2020 13:46:08
	System	08 Oct 2020 13:46:08

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:45:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'db082b9d-5f01-419e-a342-4d957afc3e71' User entered '97.9'	System	08 Oct 2020 13:46:08
	System	08 Oct 2020 13:46:08

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:45:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'db082b9d-5f01-419e-a342-4d957afc3e71' User entered 'No (N)'	System	08 Oct 2020 13:46:08
	System	08 Oct 2020 13:46:08

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:04', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'db082b9d-5f01-419e-a342-4d957afc3e71' User entered '08 Oct 2020 09:46'	System	08 Oct 2020 13:46:08
	System	08 Oct 2020 13:46:08

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 09:35'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 12:05'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:54:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cca82dd0-45e4-4fa3-a601-17b971baad4c' User entered 'Yes (Y)'	System	08 Oct 2020 21:55:00
	System	08 Oct 2020 21:55:00

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:54:50', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cca82dd0-45e4-4fa3-a601-17b971baad4c' User entered '97.2'	System	08 Oct 2020 21:55:00
	System	08 Oct 2020 21:55:00

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:54:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cca82dd0-45e4-4fa3-a601-17b971baad4c' User entered 'No (N)'	System	08 Oct 2020 21:55:00
	System	08 Oct 2020 21:55:00

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:54:58', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cca82dd0-45e4-4fa3-a601-17b971baad4c' User entered '08 Oct 2020 17:54'	System	08 Oct 2020 21:55:00
	System	08 Oct 2020 21:55:00

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 13:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 2'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:49:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '87750d09-f15e-4db6-9c75-99a5d6337b71' User entered 'Yes (Y)'	System	10 Oct 2020 00:50:09
	System	10 Oct 2020 00:50:09

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:49:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '87750d09-f15e-4db6-9c75-99a5d6337b71' User entered '97.8'	System	10 Oct 2020 00:50:09
	System	10 Oct 2020 00:50:09

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:03', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '87750d09-f15e-4db6-9c75-99a5d6337b71'	System	10 Oct 2020 00:50:09
User entered 'No (N)'	System	10 Oct 2020 00:50:09

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:07', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '87750d09-f15e-4db6-9c75-99a5d6337b71' User entered '09 Oct 2020 20:50'	System	10 Oct 2020 00:50:09
	System	10 Oct 2020 00:50:09

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 3'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:01:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1a805206-d810-4717-8be7-74857786f449' User entered 'Yes (Y)'	System	11 Oct 2020 01:03:16
	System	11 Oct 2020 01:03:16

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:08', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1a805206-d810-4717-8be7-74857786f449' User entered '97.2'	System	11 Oct 2020 01:03:16
	System	11 Oct 2020 01:03:16

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:10', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1a805206-d810-4717-8be7-74857786f449'	System	11 Oct 2020 01:03:16
User entered 'No (N)'	System	11 Oct 2020 01:03:16

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:14', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1a805206-d810-4717-8be7-74857786f449' User entered '10 Oct 2020 21:03'	System	11 Oct 2020 01:03:16
	System	11 Oct 2020 01:03:16

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 4'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:31:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cacc2763-7eb4-4f87-8ddf-9a6752a83846' User entered 'Yes (Y)'	System	12 Oct 2020 13:31:57
	System	12 Oct 2020 13:31:57

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:31:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cacc2763-7eb4-4f87-8ddf-9a6752a83846' User entered '97.1'	System	12 Oct 2020 13:31:57
	System	12 Oct 2020 13:31:57

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:31:52', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cacc2763-7eb4-4f87-8ddf-9a6752a83846'	System	12 Oct 2020 13:31:57
User entered 'No (N)'	System	12 Oct 2020 13:31:57

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:31:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cacc2763-7eb4-4f87-8ddf-9a6752a83846'	System	12 Oct 2020 13:31:57
User entered '12 Oct 2020 09:31'	System	12 Oct 2020 13:31:57

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 5'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:41:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '72dbbcc0-e9c4-49d5-a093-02ecf3e03752'	System	12 Oct 2020 23:42:28
User entered 'Yes (Y)'	System	12 Oct 2020 23:42:28

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '72dbbcc0-e9c4-49d5-a093-02ecf3e03752'	System	12 Oct 2020 23:42:28
User entered '98.6'	System	12 Oct 2020 23:42:28

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '72dbbcc0-e9c4-49d5-a093-02ecf3e03752'	System	12 Oct 2020 23:42:28
User entered 'No (N)'	System	12 Oct 2020 23:42:28

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '72dbbcc0-e9c4-49d5-a093-02ecf3e03752' User entered '12 Oct 2020 19:42'	System	12 Oct 2020 23:42:28
	System	12 Oct 2020 23:42:28

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 6'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:23:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f12295f7-0b37-4d42-8ad9-5910e37d7b5f' User entered 'Yes (Y)'	System	14 Oct 2020 01:24:24
	System	14 Oct 2020 01:24:24

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f12295f7-0b37-4d42-8ad9-5910e37d7b5f' User entered '98.1'	System	14 Oct 2020 01:24:24
	System	14 Oct 2020 01:24:24

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f12295f7-0b37-4d42-8ad9-5910e37d7b5f' User entered 'No (N)'	System	14 Oct 2020 01:24:24
	System	14 Oct 2020 01:24:24

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:22', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f12295f7-0b37-4d42-8ad9-5910e37d7b5f' User entered '13 Oct 2020 21:24'	System	14 Oct 2020 01:24:24
	System	14 Oct 2020 01:24:24

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 7'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2d95289-907a-4a29-be2c-8bb0861ec872'	System	15 Oct 2020 00:48:29
User entered 'Yes (Y)'	System	15 Oct 2020 00:48:29

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:48:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2d95289-907a-4a29-be2c-8bb0861ec872' User entered '98.0'	System	15 Oct 2020 00:48:29
	System	15 Oct 2020 00:48:29

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:48:23', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2d95289-907a-4a29-be2c-8bb0861ec872'	System	15 Oct 2020 00:48:29
User entered 'No (N)'	System	15 Oct 2020 00:48:29

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:48:28', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'e2d95289-907a-4a29-be2c-8bb0861ec872'	System	15 Oct 2020 00:48:29
User entered '14 Oct 2020 20:48'	System	15 Oct 2020 00:48:29

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:10', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd47c9fa5-7580-4edc-b813-7656e6280690'	System	08 Oct 2020 13:46:29
User entered 'None (1)'	System	08 Oct 2020 13:46:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:14', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd47c9fa5-7580-4edc-b813-7656e6280690' User entered 'No (N)'	System	08 Oct 2020 13:46:29
	System	08 Oct 2020 13:46:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd47c9fa5-7580-4edc-b813-7656e6280690' User entered 'No (N)'	System	08 Oct 2020 13:46:29
	System	08 Oct 2020 13:46:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd47c9fa5-7580-4edc-b813-7656e6280690'	System	08 Oct 2020 13:46:29
User entered 'None (1)'	System	08 Oct 2020 13:46:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd47c9fa5-7580-4edc-b813-7656e6280690' User entered '08 Oct 2020 09:46'	System	08 Oct 2020 13:46:29
	System	08 Oct 2020 13:46:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 09:35'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 12:05'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:05', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'da10334a-289c-4d4f-b471-2c320fd9a165'	System	08 Oct 2020 21:55:31
User entered 'None (1)'	System	08 Oct 2020 21:55:31

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'da10334a-289c-4d4f-b471-2c320fd9a165' User entered 'No (N)'	System	08 Oct 2020 21:55:31
	System	08 Oct 2020 21:55:31

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:14', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'da10334a-289c-4d4f-b471-2c320fd9a165' User entered 'No (N)'	System	08 Oct 2020 21:55:31
	System	08 Oct 2020 21:55:31

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'da10334a-289c-4d4f-b471-2c320fd9a165'	System	08 Oct 2020 21:55:31
User entered 'None (1)'	System	08 Oct 2020 21:55:31

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'da10334a-289c-4d4f-b471-2c320fd9a165' User entered '08 Oct 2020 17:55'	System	08 Oct 2020 21:55:31
	System	08 Oct 2020 21:55:31

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 13:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 2'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:14', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd37c77e1-031d-4090-8723-0c3949858616'	System	10 Oct 2020 00:50:34
User entered 'None (1)'	System	10 Oct 2020 00:50:34

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:17', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd37c77e1-031d-4090-8723-0c3949858616'	System	10 Oct 2020 00:50:34
User entered 'No (N)'	System	10 Oct 2020 00:50:34

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:19', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd37c77e1-031d-4090-8723-0c3949858616'	System	10 Oct 2020 00:50:34
User entered 'No (N)'	System	10 Oct 2020 00:50:34

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:23', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd37c77e1-031d-4090-8723-0c3949858616'	System	10 Oct 2020 00:50:34
User entered 'None (1)'	System	10 Oct 2020 00:50:34

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd37c77e1-031d-4090-8723-0c3949858616' User entered '09 Oct 2020 20:50'	System	10 Oct 2020 00:50:34
	System	10 Oct 2020 00:50:34

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 3'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'b21f131f-294f-4dae-846b-5cdef2e20dc4'	System	11 Oct 2020 01:03:39
User entered 'None (1)'	System	11 Oct 2020 01:03:39

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:22', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'b21f131f-294f-4dae-846b-5cdef2e20dc4'	System	11 Oct 2020 01:03:39
User entered 'No (N)'	System	11 Oct 2020 01:03:39

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:24', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'b21f131f-294f-4dae-846b-5cdef2e20dc4'	System	11 Oct 2020 01:03:39
User entered 'No (N)'	System	11 Oct 2020 01:03:39

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'b21f131f-294f-4dae-846b-5cdef2e20dc4'	System	11 Oct 2020 01:03:39
User entered 'None (1)'	System	11 Oct 2020 01:03:39

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'b21f131f-294f-4dae-846b-5cdef2e20dc4' User entered '10 Oct 2020 21:03'	System	11 Oct 2020 01:03:39
	System	11 Oct 2020 01:03:39

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 4'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:31:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '42e2732b-8bed-440b-a9e2-a7f00f4e5056'	System	12 Oct 2020 13:32:15
User entered 'None (1)'	System	12 Oct 2020 13:32:15

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:02', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '42e2732b-8bed-440b-a9e2-a7f00f4e5056'	System	12 Oct 2020 13:32:15
User entered 'No (N)'	System	12 Oct 2020 13:32:15

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:04', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '42e2732b-8bed-440b-a9e2-a7f00f4e5056'	System	12 Oct 2020 13:32:15
User entered 'No (N)'	System	12 Oct 2020 13:32:15

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:07', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '42e2732b-8bed-440b-a9e2-a7f00f4e5056'	System	12 Oct 2020 13:32:15
User entered 'None (1)'	System	12 Oct 2020 13:32:15

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '42e2732b-8bed-440b-a9e2-a7f00f4e5056' User entered '12 Oct 2020 09:32'	System	12 Oct 2020 13:32:15
	System	12 Oct 2020 13:32:15

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 5'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '12839823-52f0-45f3-8d8f-4047ba32f6dd'	System	12 Oct 2020 23:42:43
User entered 'None (1)'	System	12 Oct 2020 23:42:43

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:32', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '12839823-52f0-45f3-8d8f-4047ba32f6dd'	System	12 Oct 2020 23:42:43
User entered 'No (N)'	System	12 Oct 2020 23:42:43

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '12839823-52f0-45f3-8d8f-4047ba32f6dd'	System	12 Oct 2020 23:42:43
User entered 'No (N)'	System	12 Oct 2020 23:42:43

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '12839823-52f0-45f3-8d8f-4047ba32f6dd'	System	12 Oct 2020 23:42:43
User entered 'None (1)'	System	12 Oct 2020 23:42:43

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '12839823-52f0-45f3-8d8f-4047ba32f6dd' User entered '12 Oct 2020 19:42'	System	12 Oct 2020 23:42:43
	System	12 Oct 2020 23:42:43

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 6'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a6ee0adb-ac2b-49bf-b1e9-26f591054fb1' User entered 'None (1)'	System	14 Oct 2020 01:24:41
	System	14 Oct 2020 01:24:41

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a6ee0adb-ac2b-49bf-b1e9-26f591054fb1' User entered 'No (N)'	System	14 Oct 2020 01:24:41
	System	14 Oct 2020 01:24:41

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a6ee0adb-ac2b-49bf-b1e9-26f591054fb1' User entered 'No (N)'	System	14 Oct 2020 01:24:41
	System	14 Oct 2020 01:24:41

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:32', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a6ee0adb-ac2b-49bf-b1e9-26f591054fb1' User entered 'None (1)'	System	14 Oct 2020 01:24:41
	System	14 Oct 2020 01:24:41

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a6ee0adb-ac2b-49bf-b1e9-26f591054fb1' User entered '13 Oct 2020 21:24'	System	14 Oct 2020 01:24:41
	System	14 Oct 2020 01:24:41

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 7'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50fcb842-4ff6-4a14-a971-0c314a5c5b37'	System	15 Oct 2020 00:47:29
User entered 'None (1)'	System	15 Oct 2020 00:47:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50fcb842-4ff6-4a14-a971-0c314a5c5b37'	System	15 Oct 2020 00:47:29
User entered 'No (N)'	System	15 Oct 2020 00:47:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50fcb842-4ff6-4a14-a971-0c314a5c5b37'	System	15 Oct 2020 00:47:29
User entered 'No (N)'	System	15 Oct 2020 00:47:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:22', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50fcb842-4ff6-4a14-a971-0c314a5c5b37'	System	15 Oct 2020 00:47:29
User entered 'None (1)'	System	15 Oct 2020 00:47:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50fcb842-4ff6-4a14-a971-0c314a5c5b37'	System	15 Oct 2020 00:47:29
User entered '14 Oct 2020 20:47'	System	15 Oct 2020 00:47:29

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:33', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered 'None (0)'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:46:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8'	System	08 Oct 2020 13:47:02
User entered 'No (N)'	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T09:47:01', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '822ee818-5fa8-4177-8ec5-5bb83c3b38c8' User entered '08 Oct 2020 09:47'	System	08 Oct 2020 13:47:02
	System	08 Oct 2020 13:47:02

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 09:35'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 12:05'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:55:58', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'None (0)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:56:01', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered 'No (N)'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-08T17:56:06', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'cb867cc1-50c1-4b5c-bc76-96cb5fc767e3' User entered '08 Oct 2020 17:56'	System	08 Oct 2020 21:56:08
	System	08 Oct 2020 21:56:08

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '08 Oct 2020 13:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 2'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:40', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'None (0)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:50:56', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered 'Yes (Y)'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-09T20:51:07', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f471ab7d-0715-4949-b1a0-ead3e46c1efb' User entered '09 Oct 2020 20:51'	System	10 Oct 2020 00:51:10
	System	10 Oct 2020 00:51:10

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 3'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:46', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:47', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:50', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered 'None (0)'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:03:52', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23'	System	11 Oct 2020 01:04:04
User entered 'No (N)'	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-10T21:04:02', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '715e1056-8478-4665-9ebc-b37a068e6d23' User entered '10 Oct 2020 21:04'	System	11 Oct 2020 01:04:04
	System	11 Oct 2020 01:04:04

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 4'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:18', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:19', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:21', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:23', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:25', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'None (0)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:28', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered 'No (N)'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T09:32:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '28ddcc45-2165-43f4-a4fb-385504a60c24' User entered '12 Oct 2020 09:32'	System	12 Oct 2020 13:32:41
	System	12 Oct 2020 13:32:41

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 5'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:46', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:47', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:51', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:53', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65' User entered 'None (0)'	System	12 Oct 2020 23:43:07
	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:42:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65'	System	12 Oct 2020 23:43:07
User entered 'No (N)'	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-12T19:43:05', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'af547d4c-824b-49fa-bca8-903fc4a0fb65'	System	12 Oct 2020 23:43:07
User entered '12 Oct 2020 19:43'	System	12 Oct 2020 23:43:07

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 6'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:45', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'None (0)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:50', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered 'No (N)'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-13T21:24:56', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3078dc13-6443-4cd5-921f-c10cb3f966ee' User entered '13 Oct 2020 21:24'	System	14 Oct 2020 01:24:57
	System	14 Oct 2020 01:24:57

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	08 Oct 2020 13:19:38
User entered 'Day 7'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:32', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:33', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:36', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'None (0)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered 'No (N)'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-10-14T20:47:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1c82856b-e073-4c51-8997-dfe439058243' User entered '14 Oct 2020 20:47'	System	15 Oct 2020 00:47:46
	System	15 Oct 2020 00:47:46

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 13:19:38

US3542199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 13:19:38

US3542199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:49:34
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:31:40

US3542199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (v) (4)	21 Oct 2020 18:49:34
User entered '16 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 18:31:40

US3542199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:49:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 18:31:40

US3542199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:49:34
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:31:40

US3542199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:49:34
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 18:31:46

US3542199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	19 Oct 2020 18:31:46

US3542199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:42:07
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Oct 2020 18:54:55

US3542199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:42:07
User entered '23 Oct 2020'	Hannah Yellin (b) (4)	26 Oct 2020 18:54:55

US3542199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:42:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Oct 2020 18:54:55

US3542199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:42:07
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Oct 2020 18:54:55

US3542199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:42:07
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Oct 2020 18:55:09

US3542199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	26 Oct 2020 18:55:09

US3542199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Nov 2020 17:31:56

US3542199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered '30 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Nov 2020 17:31:56

US3542199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Nov 2020 17:31:56

US3542199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Nov 2020 17:31:56

US3542199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:07:42

US3542199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	06 Nov 2020 16:07:42

US3542199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:07:57

US3542199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered '05 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:07:57
	(b) (4)	

US3542199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered 'Clinic (Clinic)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:07:57

US3542199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'VISIT3'	System	06 Nov 2020 16:07:57

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '05 Nov 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '08:42'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '05 Nov 2020 08:42'	System	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered '98.1' F	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Oral (Oral)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:25
	(b) (4)	

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered '54'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'bpm'	System	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered '16'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'breaths/min'	System	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 22:01:58
User entered '106'	DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 22:01:58
User entered '68'	DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'mmHg'	System	06 Nov 2020 16:08:25

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01

US3542199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01

US3542199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:33

US3542199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:33

US3542199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:44

US3542199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '05 Nov 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:44

US3542199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 22:01:58
User entered '08:49'	DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:08:44

US3542199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered '05 Nov 2020 08:49'	System	06 Nov 2020 16:08:44

US3542199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:08:55

US3542199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	06 Nov 2020 16:08:55

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 64'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-12T10:10:49', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a47c6159-dc27-4ad9-8855-a07170e58c69' User entered 'No (N)'	System	12 Nov 2020 15:11:17
	System	12 Nov 2020 15:11:17

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-12T10:10:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a47c6159-dc27-4ad9-8855-a07170e58c69'	System	12 Nov 2020 15:11:17
User entered 'No (N)'	System	12 Nov 2020 15:11:17

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-12T10:11:12', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a47c6159-dc27-4ad9-8855-a07170e58c69' User entered '12 Nov 2020 10:11:12'	System	12 Nov 2020 15:11:17
	System	12 Nov 2020 15:11:17

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered 'Day 71'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-17T10:25:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '64d6d63e-e570-4d44-be15-d96fd5611cbb' User entered 'No (N)'	System	17 Nov 2020 15:25:52
	System	17 Nov 2020 15:25:52

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-17T10:25:38', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '64d6d63e-e570-4d44-be15-d96fd5611cbb' User entered 'No (N)'	System	17 Nov 2020 15:25:52
	System	17 Nov 2020 15:25:52

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-17T10:25:48', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '64d6d63e-e570-4d44-be15-d96fd5611cbb' User entered '17 Nov 2020 10:25:48'	System	17 Nov 2020 15:25:52
	System	17 Nov 2020 15:25:52

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 15:21:56

US3542199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:19:17
Data entry locked.	System	10 Sep 2020 15:21:56
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 15:21:56

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-24T07:25:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '24a2a376-3c78-4fc4-bf3c-8a18415e6d9e'	System	24 Nov 2020 12:25:43
User entered 'No (N)'	System	24 Nov 2020 12:25:43

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-24T07:25:33', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '24a2a376-3c78-4fc4-bf3c-8a18415e6d9e'	System	24 Nov 2020 12:25:43
User entered 'No (N)'	System	24 Nov 2020 12:25:43

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-24T07:25:42', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '24a2a376-3c78-4fc4-bf3c-8a18415e6d9e' User entered '24 Nov 2020 07:25:42'	System	24 Nov 2020 12:25:43
	System	24 Nov 2020 12:25:43

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-28T10:19:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50bb3bdd-a10a-40c6-94a9-c0e10f943e33' User entered 'No (N)'	System	28 Nov 2020 15:19:44

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-28T10:19:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50bb3bdd-a10a-40c6-94a9-c0e10f943e33' User entered 'No (N)'	System	28 Nov 2020 15:19:44

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-11-28T10:19:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '50bb3bdd-a10a-40c6-94a9-c0e10f943e33' User entered '28 Nov 2020 10:19:43'	System	28 Nov 2020 15:19:44
	System	28 Nov 2020 15:19:44

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-08T10:03:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5317f803-4fc8-45bf-a3d8-550d6cfb11b8' User entered 'No (N)'	System	08 Dec 2020 15:04:19
	System	08 Dec 2020 15:04:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-08T10:03:58', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5317f803-4fc8-45bf-a3d8-550d6cfb11b8' User entered 'No (N)'	System	08 Dec 2020 15:04:19
	System	08 Dec 2020 15:04:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-08T10:04:15', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5317f803-4fc8-45bf-a3d8-550d6cfb11b8' User entered '08 Dec 2020 10:04:15'	System	08 Dec 2020 15:04:19
	System	08 Dec 2020 15:04:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-14T10:13:03', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bcefed96-6086-429d-9f62-19302c0633d1' User entered 'No (N)'	System	14 Dec 2020 15:13:24
	System	14 Dec 2020 15:13:24

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-14T10:13:11', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bcefed96-6086-429d-9f62-19302c0633d1' User entered 'No (N)'	System	14 Dec 2020 15:13:24

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-14T10:13:22', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'bcefed96-6086-429d-9f62-19302c0633d1' User entered '14 Dec 2020 10:13:22'	System	14 Dec 2020 15:13:24
	System	14 Dec 2020 15:13:24

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-19T10:13:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '92e2b4f7-dbd3-4975-9dba-6dfb0b639767' User entered 'No (N)'	System	19 Dec 2020 15:13:42
	System	19 Dec 2020 15:13:42

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-19T10:13:28', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '92e2b4f7-dbd3-4975-9dba-6dfb0b639767' User entered 'No (N)'	System	19 Dec 2020 15:13:42
	System	19 Dec 2020 15:13:42

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-19T10:13:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '92e2b4f7-dbd3-4975-9dba-6dfb0b639767' User entered '19 Dec 2020 10:13:39'	System	19 Dec 2020 15:13:42
	System	19 Dec 2020 15:13:42

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-26T10:13:39', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '05a08f16-be05-4406-bf9a-51ad4dbdbb6c' User entered 'No (N)'	System	26 Dec 2020 15:13:59
	System	26 Dec 2020 15:13:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-26T10:13:47', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '05a08f16-be05-4406-bf9a-51ad4dbdbb6c' User entered 'No (N)'	System	26 Dec 2020 15:13:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2020-12-26T10:13:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '05a08f16-be05-4406-bf9a-51ad4dbdbb6c' User entered '26 Dec 2020 10:13:54'	System	26 Dec 2020 15:13:59
	System	26 Dec 2020 15:13:59

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-02T10:13:29', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3cc272cf-4844-4d6c-b46e-16103e95dbf8' User entered 'No (N)'	System	02 Jan 2021 15:13:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-02T10:13:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3cc272cf-4844-4d6c-b46e-16103e95dbf8'	System	02 Jan 2021 15:13:47
User entered 'No (N)'	System	02 Jan 2021 15:13:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-02T10:13:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '3cc272cf-4844-4d6c-b46e-16103e95dbf8' User entered '02 Jan 2021 10:13:43'	System	02 Jan 2021 15:13:47
	System	02 Jan 2021 15:13:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-09T10:25:35', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '7164178e-cd4c-4a16-85db-caf552b5aaaf' User entered 'No (N)'	System	09 Jan 2021 15:25:48
	System	09 Jan 2021 15:25:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-09T10:25:41', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '7164178e-cd4c-4a16-85db-caf552b5aaaf' User entered 'No (N)'	System	09 Jan 2021 15:25:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-09T10:25:46', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '7164178e-cd4c-4a16-85db-caf552b5aaaf' User entered '09 Jan 2021 10:25:46'	System	09 Jan 2021 15:25:48
	System	09 Jan 2021 15:25:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-16T10:14:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5b9c0b38-a0b8-43db-a46a-7bf67f9a6806' User entered 'No (N)'	System	23 Jan 2021 15:14:30
	System	23 Jan 2021 15:14:30

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-16T10:14:54', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5b9c0b38-a0b8-43db-a46a-7bf67f9a6806' User entered 'No (N)'	System	23 Jan 2021 15:14:30

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-16T10:15:02', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '5b9c0b38-a0b8-43db-a46a-7bf67f9a6806' User entered '16 Jan 2021 10:15:02'	System	23 Jan 2021 15:14:30
	System	23 Jan 2021 15:14:30

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-23T10:14:34', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '0025bf3d-ad40-4436-ada6-a07ed779463c' User entered 'No (N)'	System	23 Jan 2021 15:14:46
	System	23 Jan 2021 15:14:46

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-23T10:14:40', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '0025bf3d-ad40-4436-ada6-a07ed779463c' User entered 'No (N)'	System	23 Jan 2021 15:14:46

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-23T10:14:44', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '0025bf3d-ad40-4436-ada6-a07ed779463c' User entered '23 Jan 2021 10:14:44'	System	23 Jan 2021 15:14:46
	System	23 Jan 2021 15:14:46

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-30T07:01:16', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9c068e12-ccd7-4a2f-8163-6378e86ffcdf' User entered 'Yes (Y)'	System	30 Jan 2021 12:01:45

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-30T07:01:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9c068e12-ccd7-4a2f-8163-6378e86ffcdf' User entered 'No (N)'	System	30 Jan 2021 12:01:45

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-30T07:01:27', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9c068e12-ccd7-4a2f-8163-6378e86ffcdf' User entered 'No (N)'	System	30 Jan 2021 12:01:45

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-30T07:01:31', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9c068e12-ccd7-4a2f-8163-6378e86ffcdf' User entered 'No (N)'	System	30 Jan 2021 12:01:45

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-01-30T07:01:43', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '9c068e12-ccd7-4a2f-8163-6378e86ffcdf' User entered '30 Jan 2021 07:01:43'	System	30 Jan 2021 12:01:45
	System	30 Jan 2021 12:01:45

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-09T17:59:26', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd35aa8b8-1a52-433a-8c43-7c646f7fc832'	System	09 Feb 2021 22:59:41
User entered 'No (N)'	System	09 Feb 2021 22:59:41

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-09T17:59:32', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd35aa8b8-1a52-433a-8c43-7c646f7fc832'	System	09 Feb 2021 22:59:41
User entered 'No (N)'	System	09 Feb 2021 22:59:41

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-09T17:59:37', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'd35aa8b8-1a52-433a-8c43-7c646f7fc832'	System	09 Feb 2021 22:59:41
User entered '09 Feb 2021 17:59:37'	System	09 Feb 2021 22:59:41

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-15T12:02:13', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '746d8120-ff69-42cc-aad9-f3c7af348dda' User entered 'No (N)'	System	22 Feb 2021 14:01:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-15T12:02:20', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '746d8120-ff69-42cc-aad9-f3c7af348dda' User entered 'No (N)'	System	22 Feb 2021 14:01:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-15T12:02:30', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '746d8120-ff69-42cc-aad9-f3c7af348dda' User entered '15 Feb 2021 12:02:30'	System	22 Feb 2021 14:01:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-22T09:01:55', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '2e7b8cbb-061a-4364-a324-4b2792f2ef97' User entered 'No (N)'	System	23 Feb 2021 19:37:04
	System	23 Feb 2021 19:37:04

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-22T09:01:59', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '2e7b8cbb-061a-4364-a324-4b2792f2ef97'	System	23 Feb 2021 19:37:04
User entered 'No (N)'	System	23 Feb 2021 19:37:04

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-22T09:02:08', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '2e7b8cbb-061a-4364-a324-4b2792f2ef97'	System	23 Feb 2021 19:37:04
User entered '22 Feb 2021 09:02:08'	System	23 Feb 2021 19:37:04

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-28T10:17:06-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'df5ebbf8-36da-4cfe-bf54-94f7b5d5fe46'	System	10 Mar 2021 15:21:47
User entered 'No (N)'	System	10 Mar 2021 15:21:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-28T10:17:12-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'df5ebbf8-36da-4cfe-bf54-94f7b5d5fe46'	System	10 Mar 2021 15:21:47
User entered 'No (N)'	System	10 Mar 2021 15:21:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-28T10:17:16-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'df5ebbf8-36da-4cfe-bf54-94f7b5d5fe46'	System	10 Mar 2021 15:21:47
User entered '28 Feb 2021 10:17:16'	System	10 Mar 2021 15:21:47

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-10T10:21:46-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6c9c3ec9-75e1-4470-a359-2c68a99880cc' User entered 'No (N)'	System	10 Mar 2021 15:21:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-10T10:21:51-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6c9c3ec9-75e1-4470-a359-2c68a99880cc' User entered 'No (N)'	System	10 Mar 2021 15:21:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-10T10:21:55-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '6c9c3ec9-75e1-4470-a359-2c68a99880cc' User entered '10 Mar 2021 10:21:55'	System	10 Mar 2021 15:21:57
	System	10 Mar 2021 15:21:57

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-15T12:30:41-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4483f289-b392-4b9c-abf4-c85a82d79f10'	System	20 Mar 2021 15:16:00
User entered 'No (N)'	System	20 Mar 2021 15:16:00

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-15T12:30:47-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4483f289-b392-4b9c-abf4-c85a82d79f10'	System	20 Mar 2021 15:16:00
User entered 'No (N)'	System	20 Mar 2021 15:16:00

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-15T12:30:51-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4483f289-b392-4b9c-abf4-c85a82d79f10'	System	20 Mar 2021 15:16:00
User entered '15 Mar 2021 12:30:51'	System	20 Mar 2021 15:16:00

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-20T11:16:01-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4a6a12a8-48fe-45aa-9fa4-1686b384c29e' User entered 'No (N)'	System	20 Mar 2021 15:16:12
	System	20 Mar 2021 15:16:12

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-20T11:16:05-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4a6a12a8-48fe-45aa-9fa4-1686b384c29e'	System	20 Mar 2021 15:16:12
User entered 'No (N)'	System	20 Mar 2021 15:16:12

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-20T11:16:09-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '4a6a12a8-48fe-45aa-9fa4-1686b384c29e'	System	20 Mar 2021 15:16:12
User entered '20 Mar 2021 11:16:09'	System	20 Mar 2021 15:16:12

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-29T11:16:31-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f0aafb51-2403-4606-ae50-7b0eb5d14734' User entered 'No (N)'	System	05 Apr 2021 19:05:26
	System	05 Apr 2021 19:05:26

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-29T11:16:36-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f0aafb51-2403-4606-ae50-7b0eb5d14734' User entered 'No (N)'	System	05 Apr 2021 19:05:26
	System	05 Apr 2021 19:05:26

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-03-29T11:16:39-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'f0aafb51-2403-4606-ae50-7b0eb5d14734'	System	05 Apr 2021 19:05:26
User entered '29 Mar 2021 11:16:39'	System	05 Apr 2021 19:05:26

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-05T15:03:48-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85e82e17-87be-4ae7-883a-98ebcca716b1' User entered 'No (N)'	System	05 Apr 2021 19:05:39

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-05T15:03:50-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85e82e17-87be-4ae7-883a-98ebcca716b1' User entered 'No (N)'	System	05 Apr 2021 19:05:39

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-05T15:03:55-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '85e82e17-87be-4ae7-883a-98ebcca716b1' User entered '05 Apr 2021 15:03:55'	System	05 Apr 2021 19:05:39
	System	05 Apr 2021 19:05:39

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-14T12:04:31-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a7b6f07a-5a29-4d47-9c2a-f2855b22d5e3'	System	14 Apr 2021 18:41:40
User entered 'No (N)'	System	14 Apr 2021 18:41:40

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-14T12:04:36-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a7b6f07a-5a29-4d47-9c2a-f2855b22d5e3'	System	14 Apr 2021 18:41:40
User entered 'No (N)'	System	14 Apr 2021 18:41:40

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-14T12:04:40-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'a7b6f07a-5a29-4d47-9c2a-f2855b22d5e3'	System	14 Apr 2021 18:41:40
User entered '14 Apr 2021 12:04:40'	System	14 Apr 2021 18:41:40

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-17T23:20:37-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1e631981-dcd8-4a7b-abee-6335d777fc0d' User entered 'No (N)'	System	18 Apr 2021 03:20:48
	System	18 Apr 2021 03:20:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-17T23:20:41-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1e631981-dcd8-4a7b-abee-6335d777fc0d'	System	18 Apr 2021 03:20:48
User entered 'No (N)'	System	18 Apr 2021 03:20:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-17T23:20:46-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '1e631981-dcd8-4a7b-abee-6335d777fc0d' User entered '17 Apr 2021 23:20:46'	System	18 Apr 2021 03:20:48
	System	18 Apr 2021 03:20:48

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-27T18:45:46-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '252eeb1a-d399-4301-ba87-da2a84a446f5' User entered 'No (N)'	System	28 Apr 2021 23:39:19
	System	28 Apr 2021 23:39:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

Have you been exposed to someone with 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 (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-27T18:45:54-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '252eeb1a-d399-4301-ba87-da2a84a446f5'	System	28 Apr 2021 23:39:19
User entered 'No (N)'	System	28 Apr 2021 23:39:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-04-27T18:45:58-04:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: '252eeb1a-d399-4301-ba87-da2a84a446f5'	System	28 Apr 2021 23:39:19
User entered '27 Apr 2021 18:45:58'	System	28 Apr 2021 23:39:19

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 06:58:53

US3542199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:53
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 06:58:53

US3542199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:08

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 10:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-28T10:16:52-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'be72b60f-709d-4ad6-90b7-060f54bcb536'	System	28 Feb 2021 15:17:20
User entered 'No (N)'	System	28 Feb 2021 15:17:20

US3542199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64009948-5CFF-4EB0-8A10-F76975896BD6)', Time: '2021-02-28T10:16:59-05:00', User OID: 'PatientReportedOutcome (US3542199)', ODM File OID: 'be72b60f-709d-4ad6-90b7-060f54bcb536' User entered '28 Feb 2021 10:16:59'	System	28 Feb 2021 15:17:20
	System	28 Feb 2021 15:17:20

US3542199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:10:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:50:37

US3542199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:10:13
User entered '03 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:50:37

US3542199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:10:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	03 Dec 2020 17:50:37

US3542199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:10:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:50:37

US3542199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:10:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	03 Dec 2020 17:50:41

US3542199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:54:01
User entered 'l'	System	03 Dec 2020 17:50:41

US3542199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	08 Jan 2021 19:53:54

US3542199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	08 Jan 2021 19:53:54

US3542199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hannah Yellin (b) (4)	08 Jan 2021 19:53:54

US3542199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered empty.	(b) (4) Hannah Yellin (b) (4)	08 Jan 2021 19:53:54

US3542199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	08 Jan 2021 19:54:05

US3542199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered 'l'	System	08 Jan 2021 19:54:05

US3542199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:04:21

US3542199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:04:21

US3542199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 19:04:21

US3542199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 19:04:21

US3542199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:04:26

US3542199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered 'l'	System	08 Feb 2021 19:04:26

US3542199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:21:06

US3542199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered '05 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:21:06

US3542199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:21:06

US3542199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:21:06

US3542199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:21:11

US3542199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered 'l'	System	05 Mar 2021 17:21:11

US3542199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:28:22

US3542199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:22

US3542199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:22

US3542199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered 'VISIT4'	System	01 Apr 2021 18:28:22

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered empty.	System	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered empty.	System	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered empty.	System	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered empty.	System	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered empty.	System	01 Apr 2021 18:28:30

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01

US3542199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01

US3542199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:28:36

US3542199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:28:36

US3542199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:28:57

US3542199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 18:28:57

US3542199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered '08:45'	(b) (4), (b) (6)	01 Apr 2021 18:28:57

US3542199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered '01 Apr 2021 08:45'	System	01 Apr 2021 18:28:57

US3542199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:29:05

US3542199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:13:01
User entered 'I'	System	01 Apr 2021 18:29:05

US3542199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:07:48

US3542199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:07:48

US3542199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:07:48

US3542199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 18:07:48

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:10:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:24:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:45:06

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:10:53
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Mar 2021 15:24:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:45:06

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:18:10
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:18:10
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'I'	System	04 Jan 2021 18:10:10

US3542199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'I'	System	04 Jan 2021 18:10:10

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	04 Jan 2021 18:13:23
DataPoint set to visible.	System	04 Jan 2021 18:10:10

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	04 Jan 2021 18:13:23
DataPoint set to visible.	System	04 Jan 2021 18:10:10

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '08:40'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '04 Jan 2021 08:40'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '98.3' F	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '50'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'bpm'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'breaths/min'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '118'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '66'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	04 Jan 2021 18:13:23
DataPoint set to visible.	System	04 Jan 2021 18:10:10

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '09:32'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '04 Jan 2021 09:32'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '98.5' F	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '45'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'bpm'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'breaths/min'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '124'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '71'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:13:23

US3542199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	04 Jan 2021 18:13:23

US3542199

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:38

US3542199

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:10:38

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mRNA-1273'	System	04 Jan 2021 18:15:11
DataPoint set to visible.	System	04 Jan 2021 18:10:10

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '09:02'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '04 Jan 2021 09:02'	System	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'ONCE'	System	04 Jan 2021 18:15:11

US3542199

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

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'INTRAMUSCULAR'	System	04 Jan 2021 18:15:11

US3542199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:22

US3542199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:03:35
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 15:44:21
User entered '04 Jan 2021'	Erika Faust (b) (4)	04 Jan 2021 18:14:22

US3542199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered '08:58'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:22

US3542199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '04 Jan 2021 08:58'	System	04 Jan 2021 18:14:22

US3542199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:33

US3542199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '04 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:33

US3542199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered '08:59'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:33

US3542199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '04 Jan 2021 08:59'	System	04 Jan 2021 18:14:33

US3542199

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

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Jan 2021 18:14:38

US3542199

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

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'I'	System	04 Jan 2021 18:14:38

US3542199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Jan 2021 17:50:13

US3542199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered '12 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Jan 2021 17:50:13

US3542199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	13 Jan 2021 17:50:13

US3542199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Jan 2021 17:50:13

US3542199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Jan 2021 17:50:18

US3542199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'l'	System	13 Jan 2021 17:50:18

US3542199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'I'	System	13 Jan 2021 17:50:18
DataPoint set to visible.	System	13 Jan 2021 17:50:18

US3542199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:00

US3542199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '29 Jan 2021'	(b) (4) Erika Faust (b) (4)	29 Jan 2021 16:44:00

US3542199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:00

US3542199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'OLD29'	System	29 Jan 2021 16:44:00

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '29 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '09:10'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '29 Jan 2021 09:10'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '97.9' F	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '46'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'bpm'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'breaths/min'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '135'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '76'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '29 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '09:57'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '29 Jan 2021 09:57'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '98.7' F	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '45'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'bpm'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'breaths/min'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '117'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '69'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mmHg'	System	29 Jan 2021 16:44:59

US3542199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:08

US3542199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '29 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:08

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered empty.	(b) (4) Erika Faust (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'mRNA-1273'	System	29 Jan 2021 16:45:19
DataPoint set to visible.	System	13 Jan 2021 17:50:18

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '29 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered '09:20'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '29 Jan 2021 09:20'	System	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'ONCE'	System	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 16:45:19

US3542199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:22:50
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Jan 2021 16:45:25

US3542199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'l'	System	29 Jan 2021 16:45:25

US3542199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:05:51

US3542199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:05:51

US3542199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:05:51

US3542199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 19:05:51

US3542199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 19:05:59

US3542199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'l'	System	08 Feb 2021 19:05:59

US3542199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:20

US3542199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered '05 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:20

US3542199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:20

US3542199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered 'OLD57'	System	05 Mar 2021 17:20:20

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered empty.	System	05 Mar 2021 17:20:05

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29

US3542199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29

US3542199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:19:58

US3542199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:19:58

US3542199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:19:53

US3542199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered '05 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:19:53

US3542199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:54
User entered '09:06'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:19:53

US3542199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:29
User entered '05 Mar 2021 09:06'	System	05 Mar 2021 17:19:53

US3542199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:09:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:04
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:19
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:16:12

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:23
User entered 'USA-US084-2021-mRNA-1273-P301000007'	System	09 Mar 2021 15:23:17
User entered 'New'	(b) (4), (b) (6)	09 Mar 2021 15:23:17

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User closed query 'Per MM: Please confirm this does not meet the definition of an SAE.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:44:44
Query 'Per MM: Please confirm this does not meet the definition of an SAE.' answered with 'Updated to SAE' (Site from DM).	Elissa Malkin (b) (4)	08 Mar 2021 20:34:26
User opened query 'Per MM: Please confirm this does not meet the definition of an SAE.' (Site from DM).	(b) (4)	04 Feb 2021 07:31:49
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
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 cell carcinoma, LLT: Renal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 20:43:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	04 Jan 2021 20:43:32
Data point term sent to Coder	System	04 Jan 2021 20:42:49
Coding entries removed.	David Diemert (b) (4)	04 Jan 2021 20:41:49
Signature has been broken.	(b) (4)	04 Jan 2021 20:41:49
User entered 'RENAL CELL CARCINOMA' reason for change: New Information	David Diemert (b) (4)	04 Jan 2021 20:41:49
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal disorders NEC, PT: Renal mass, LLT: Renal mass - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 16:19:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Nov 2020 16:19:18
Data point term sent to Coder	System	06 Nov 2020 16:18:11
User entered 'renal mass'	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	13 Jan 2021 17:52:23
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	13 Jan 2021 17:52:23
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '20 Oct 2020'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	04 Jan 2021 20:41:49
	(b) (4)	
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4)	04 Jan 2021 20:41:49
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:29:44
	(b) (4)	
User entered '29 Oct 2020' reason for change: New Information	Hannah Yellin (b) (4)	10 Mar 2021 18:29:44
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:43:45
	(b) (4)	
Signature has been broken.	Erika Faust (b) (4)	13 Jan 2021 17:52:23
	(b) (4)	
User entered '27 Oct 2020' reason for change: Data Entry Error	Erika Faust (b) (4)	13 Jan 2021 17:52:23
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	04 Jan 2021 20:41:49
	(b) (4)	
User entered '27 Nov 2020' reason for change: New Information	David Diemert (b) (4)	04 Jan 2021 20:41:49
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'No (N)'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	09 Mar 2021 16:52:27
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	09 Mar 2021 16:52:27
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Mar 2021 20:34:11
Signature has been broken.	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User entered '27 Oct 2020' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User entered '29 Oct 2020' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	09 Mar 2021 16:52:27
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	09 Mar 2021 16:52:27
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Not Related (NOT RELATED)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Not Related (NOT RELATED)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 16:27:43
User closed query 'PV Query: As the last dose of placebo was given on 08 Oct 2020 after the event onset (02 Oct 2020), please consider updating the action taken with study drug from "not applicable" to "none". If not so, please clarify.' (Site from Safety). Query 'PV Query: As the last dose of placebo was given on 08 Oct 2020 after the event onset (02 Oct 2020), please consider updating the action taken with study drug from "not applicable" to "none". If not so, please clarify.' answered with 'updated' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:49:44
Signature has been broken.	Elissa Malkin (b) (4)	16 Mar 2021 16:28:54
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4)	16 Mar 2021 16:28:43
User opened query 'PV Query: As the last dose of placebo was given on 08 Oct 2020 after the event onset (02 Oct 2020), please consider updating the action taken with study drug from "not applicable" to "none". If not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:57:00
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Not Applicable (NOT APPLICABLE)'	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'I'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

US3542199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:47:10
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	04 Jan 2021 20:41:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	David Diemert (b) (4)	04 Jan 2021 20:41:49
New Information	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:56:49
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 13:52:22
Signature has been broken.	(b) (4) David Diemert (b) (4)	01 Apr 2021 13:51:13
User entered 'RENAL MASS WAS DETECTED ON AN MRI THAT WAS DONE TO INVESTIGATE LIVER CYSTS FOUND ON ROUTINE ABDOMINAL ULTRASOUND (16SEP2020) ORDERED BY PCP TO INVESTIGATE MILDLY ELEVATED LIVER ENZYMES (VALUES NOT AVAILABLE). THE MRI ON 02OCT2020 CONFIRMED BENIGN LIVER CYSTS BUT INCIDENTALLY REVEALED A LEFT UPPER POLE KIDNEY MASS. PARTICIPANT SUBSEQUENTLY UNDERWENT A LAPAROSCOPIC PARTIAL NEPHRECTOMY ON 27OCT2020. PATHOLOGY SHOWED RENAL CELL CARCINOMA AND THAT THE ENTIRE LESION WAS REMOVED. NO FURTHER TREATMENT INDICATED. PARTICIPANT HOSPITALIZED 27OCT2020 THRU 29OCT2020 FOR THE PROCEDURE AND ASSOCIATED PAIN MANAGEMENT. HE RECOVERED WELL AND WITHOUT INCIDENT OR COMPLICATIONS.' reason for change: New Information	David Diemert (b) (4)	01 Apr 2021 13:51:13
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 13:35:48
DataPoint Un-verified.	(b) (4) David Diemert (b) (4)	01 Apr 2021 13:35:25
Signature has been broken.	(b) (4) David Diemert (b) (4)	01 Apr 2021 13:35:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'RENAL MASS WAS DETECTED ON an MRI that was done to investigate liver cysts found on ROUTINE ABDOMINAL ULTRASOUND ORDERED BY PCP TO INVESTIGATE MILDLY ELEVATED LIVER ENZYMES (VALUES NOT AVAILABLE). THE MRI on 02OCT2020 confirmed BENIGN LIVER CYSTS BUT INCIDENTALLY revealed A LEFT upper pole KIDNEY MASS. PARTICIPANT SUBSEQUENTLY UNDERWENT A LAPAROSCOPIC PARTIAL NEPHRECTOMY ON 27OCT2020. PATHOLOGY SHOWED RENAL CELL CARCINOMA AND THAT THE ENTIRE LESION WAS REMOVED. NO FURTHER TREATMENT INDICATED. PARTICIPANT HOSPITALIZED 27OCT2020 THRU 29OCT2020 FOR THE PROCEDURE AND ASSOCIATED PAIN MANAGEMENT. HE RECOVERED WELL AND WITHOUT INCIDENT OR COMPLICATIONS.' reason for change: New Information DataPoint Verified.	David Diemert (b) (4) (b) (4)	01 Apr 2021 13:35:25
User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 16:19:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	David Diemert (b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:21
User closed query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:55:25
Query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly. ' answered with 'Updated.' (Site from Safety).	David Diemert (b) (4) (b) (4)	26 Mar 2021 22:04:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Details added.' (Site from Safety). Signature has been broken.	David Diemert (b) (4)	26 Mar 2021 22:03:51
	David Diemert (b) (4)	26 Mar 2021 22:01:42
User entered 'RENAL MASS WAS DETECTED ON ROUTINE abdominal ultrasound ordered by PCP to investigate mildly elevated liver enzymes (values not available). This revealed benign liver cysts but incidentally a left kidney mass. MRI on 02OCT2020 confirmed left upper pole renal mass. PARTICIPANT SUBSEQUENTLY UNDERWENT A LAPAROSCOPIC PARTIAL NEPHRECTOMY ON 27OCT2020. PATHOLOGY SHOWED RENAL CELL CARCINOMA AND THAT THE ENTIRE LESION WAS REMOVED. NO FURTHER TREATMENT INDICATED. PARTICIPANT HOSPITALIZED 27OCT2020 THRU 29OCT2020 FOR THE PROCEDURE AND ASSOCIATED PAIN MANAGEMENT. He recovered well and without incident or complications.' reason for change: Per Query Resolution	David Diemert (b) (4)	26 Mar 2021 22:01:42
User opened query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:57:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 15:57:07
	David Diemert (b) (4)	17 Mar 2021 16:27:43

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:50:12
User closed query 'PV Query: Did the subject have any medical history of renal mass? Was the SAE considered a worsening of the subject's medical history? Please confirm your response.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:50:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:50:04
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)	17 Mar 2021 14:49:52
Query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly.' answered with 'This is not known and not sure how it is relevant given you have the hospital records/pathology and this is not related to vaccination' (Site from Safety).	Elissa Malkin (b) (4)	16 Mar 2021 17:48:26
Signature has been broken.	David Diemert (b) (4)	16 Mar 2021 17:09:25
User entered 'RENAL MASS WAS DETECTED ON ROUTINE IMAGING AND PARTICIPANT SUBSEQUENTLY UNDERWENT A LAPAROSCOPIC PARTIAL NEPHRECTOMY ON 27OCT2020. PATHOLOGY SHOWED RENAL CELL CARCINOMA AND THAT THE ENTIRE LESION WAS REMOVED. NO FURTHER TREATMENT INDICATED. PARTICIPANT HOSPITALIZED 27OCT2020 THRU 29OCT2020 FOR THE PROCEDURE AND ASSOCIATED PAIN MANAGEMENT.' reason for change: Data Entry Error	David Diemert (b) (4)	16 Mar 2021 17:09:25

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Laboratory and diagnostic test results were faxed to Moderna Safety on 10MAR2021' (Site from Safety).	Elissa Malkin (b) (4)	16 Mar 2021 16:32:38
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 'COVID-19 testing was not done during hospital admission' (Site from Safety).	Elissa Malkin (b) (4)	16 Mar 2021 16:31:55
Query 'PV Query: Did the subject have any medical history of renal mass? Was the SAE considered a worsening of the subject's medical history? Please confirm your response.' answered with 'No medical history of renal mass' (Site from Safety).	Elissa Malkin (b) (4)	16 Mar 2021 16:30:29
User opened query 'PV Query: Please provide the date and details of the imaging done to detect the renal mass. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:58:47
User opened query 'PV Query: Did the subject have any medical history of renal mass? Was the SAE considered a worsening of the subject's medical history? Please confirm your response.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:58:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:57:55
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)	16 Mar 2021 14:57:42

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User entered 'Renal mass was detected on routine imaging and participant subsequently underwent a laparoscopic partial nephrectomy on 27OCT2020. Pathology showed renal cell carcinoma and that the entire lesion was removed. No further treatment indicated. Participant hospitalized 27OCT2020 thru 29OCT2020 for the procedure and associated pain management.' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	08 Mar 2021 20:34:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	06 Nov 2020 16:17:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 20:34:11
User entered '0'	System	06 Nov 2020 16:17:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 16:17:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 16:52:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:09:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:04
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:19:29
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:09:27

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 17:10:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:10:40
Data point term sent to Coder	System	11 Sep 2020 17:09:55
User entered 'atenolol'	Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'cardiomyopathy'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '25'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2004'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:09:54

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:15:49
Data point term sent to Coder	System	11 Sep 2020 17:10:57
User entered 'rosuvastatin'	Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'cardiomyopathy'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '10'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per CDM CLR: Con Med start date is prior to the start date of the Med History condition of CARDIOMYOPATHY-UN UNK 2004. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:21:15
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Query 'Per CDM CLR: Con Med start date is prior to the start date of the Med History condition of CARDIOMYOPATHY-UN UNK 2004. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Corrected.' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 21:31:21
Signature has been broken.	David Diemert (b) (4)	11 Nov 2020 21:31:14
User entered 'UN UNK 2004' reason for change: Data Entry Error	David Diemert (b) (4)	11 Nov 2020 21:31:14
User opened query 'Per CDM CLR: Con Med start date is prior to the start date of the Med History condition of CARDIOMYOPATHY-UN UNK 2004. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:41:18
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2000'	Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:10:16

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:11:46
Data point term sent to Coder	System	11 Sep 2020 17:10:57
User entered 'aspirin'	Taylor Ladson (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'cardiomyopathy'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '81'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2004'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	26 Oct 2020 18:57:19
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	26 Oct 2020 18:57:19
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4)	
	Taylor Ladson (b) (4)	11 Sep 2020 17:10:35
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	26 Oct 2020 18:57:19
User entered '20 Oct 2020' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	26 Oct 2020 18:57:19
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	11 Sep 2020 17:10:35
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
User entered 'I'	System	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
User entered 'I'	System	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:07:03
User entered '804 (804)'	System	11 Sep 2020 17:10:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:12:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:12:35
Data point term sent to Coder	System	11 Sep 2020 17:12:00
User entered 'vitamin d'	Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:04:43
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:53:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'general health'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '25'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'ug (ug)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:11:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:07:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:07:34
Data point term sent to Coder	System	11 Nov 2020 21:57:57
Coding entries removed.	David Diemert (b) (4)	11 Nov 2020 21:57:25
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 10:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 10:08:53
Data point term sent to Coder	System	11 Sep 2020 17:12:01
User entered 'fexafenidine'	Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:36:01
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 21:57:35
Signature has been broken.	David Diemert (b) (4)	11 Nov 2020 21:57:25
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Nov 2020 21:57:25
User opened query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:06:42
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'allergies'	Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '180'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	16 Oct 2020 13:59:13
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	16 Oct 2020 13:59:13
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
	(b) (4)	
User entered 'ug (ug)'	Taylor Ladson (b) (4)	11 Sep 2020 17:11:42
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:11:42

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 21:58:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 21:58:36
Data point term sent to Coder	System	11 Nov 2020 21:57:57
Coding entries removed.	David Diemert (b) (4)	11 Nov 2020 21:57:48
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:13:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:13:45
Data point term sent to Coder	System	11 Sep 2020 17:13:07
User entered 'azelastine'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:42:44
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 21:57:53
Signature has been broken.	David Diemert (b) (4)	11 Nov 2020 21:57:48
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Nov 2020 21:57:48
User opened query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:07:31
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'allergies'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:02:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are two dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 10:16:20
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are two dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	21 Dec 2020 20:24:30
Signature has been broken.	Elissa Malkin (b) (4)	21 Dec 2020 20:23:54
User entered '137' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	21 Dec 2020 20:23:54
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are two dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:57:45
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '1'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:02:40
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	21 Dec 2020 20:23:54
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	21 Dec 2020 20:23:54
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'puff (PUFF)'	(b) (4)	
	Taylor Ladson (b) (4)	11 Sep 2020 17:12:13
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Nasal (NASAL)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:12:13

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: OLOPATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:54:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:54:07
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Data point term sent to Coder	System	11 Nov 2020 22:02:05
Coding entries removed.	David Diemert (b) (4)	11 Nov 2020 22:01:34
Coding entries removed.	David Diemert (b) (4)	11 Nov 2020 22:01:34
Signature has been broken.	David Diemert (b) (4)	11 Nov 2020 22:01:34
User entered 'OLOPADINE 0.01%' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Nov 2020 22:01:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: OLOPATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:45:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:45:47
Data point term sent to Coder	System	11 Sep 2020 17:13:10
User entered 'olopadine'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:35:47
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 22:01:40
Signature has been broken.	David Diemert (b) (4)	11 Nov 2020 22:01:34
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Nov 2020 22:01:34
User opened query 'Per CDM CLR* Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:09:03
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'allergies'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per CDM CLR: Please note, 0.01 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Nov 2020 07:41:01
Query 'Per CDM CLR: Please note, 0.01 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	(b) (4)
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4)	11 Nov 2020 22:01:34
User opened query 'Per CDM CLR: Please note, 0.01 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	19 Oct 2020 06:41:51
User entered '.01%'	David Diemert (b) (4)	14 Sep 2020 05:10:26
	(b) (4)	(b) (4)
	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:01:34
	(b) (4)	
User entered 'Application' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Nov 2020 22:01:34
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 05:10:26
	(b) (4)	
User entered 'drop'	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:01:34
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	David Diemert (b) (4)	11 Nov 2020 22:01:34
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Intraocular (INTRAOCULAR)'	(b) (4)	
	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:01:34
User entered 'Ophthalmic' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:01:34
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	11 Sep 2020 17:12:52
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered '0'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered empty.	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:10:26
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:12:52

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:19:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:19:28
Data point term sent to Coder	System	06 Nov 2020 16:10:54
User entered 'heparin'	DeEnna Wedding (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'partial nephrectomy'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Other (OTHER)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'three times daily (TID)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '27 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '29 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
User entered '3'	System	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
User entered 'I'	System	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:05:13
User entered '804 (804)'	System	06 Nov 2020 16:10:39

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:13:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:13:29
Data point term sent to Coder	System	06 Nov 2020 16:11:57
User entered 'cefazolin'	DeEnna Wedding (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'partial nephrectomy'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Other (OTHER)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'three times daily (TID)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '27 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '29 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
User entered '3'	System	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
User entered 'I'	System	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:10:42
User entered '804 (804)'	System	06 Nov 2020 16:11:32

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:13:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:13:18
Data point term sent to Coder	System	06 Nov 2020 16:12:59
User entered 'dilaudid'	DeEnna Wedding (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'partial nephrectomy'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Other (OTHER)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'three times daily (TID)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '27 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '28 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
User entered '3'	System	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
User entered 'I'	System	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:27
User entered '804 (804)'	System	06 Nov 2020 16:12:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Nov 2020 08:36:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:36:29
Data point term sent to Coder	System	06 Nov 2020 16:14:00
User entered 'toradol'	DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'partial nephrectomy'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User entered '7.5' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'UNK'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User entered 'mg (mg)' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Other (OTHER)'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User entered empty; reason for change New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
	(b) (4)	
User entered 'UNK'	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User entered 'other (OTHER)' reason for change:	(b) (4)	
New Information	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'three times daily (TID)'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User entered 'Every 6 hours' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:27:24
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '27 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '29 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
User entered empty.	System	10 Mar 2021 18:27:24
User entered '3'	System	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
User entered empty.	System	10 Mar 2021 18:27:24
User entered 'I'	System	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:32:16
User entered empty.	System	10 Mar 2021 18:27:24
User entered '804 (804)'	System	06 Nov 2020 16:13:01

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:15:20
Data point term sent to Coder	System	06 Nov 2020 16:14:01
User entered 'aspirin'	DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'cardiomyopathy'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '81'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'once daily (QD)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '31 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 16:13:35

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SAG 3V, PRODUCTSYNONYM: FLUAD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:16:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:16:18
Data point term sent to Coder	System	06 Nov 2020 16:15:08
User entered 'fluad'	DeEnna Wedding (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'influenza prophylaxis'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0.5'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'mL (mL)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'once (ONCE)'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '22 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered '22 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 22:02:07
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
User entered empty.	System	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
User entered empty.	System	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:21:33
User entered empty.	System	06 Nov 2020 16:14:12

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 14:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 14:46:49
Data point term sent to Coder	System	11 Mar 2021 14:45:50
User entered 'Acetaminophen'	Erika Faust (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Left partial nephrectomy'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '650'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'other (OTHER)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Every 6 hours'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 06:58:00
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 18:09:28
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Updated' (Site from DM).	David Diemert (b) (4)	24 Mar 2021 18:07:13
Signature has been broken.	David Diemert (b) (4)	24 Mar 2021 18:06:56
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4)	24 Mar 2021 18:06:56
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:00:27
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Yes (Y)'	Erika Faust (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 18:09:28
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 18:06:56
	(b) (4)	
User entered '01 Nov 2020' reason for change: New Information	David Diemert (b) (4)	24 Mar 2021 18:06:56
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	11 Mar 2021 17:56:18
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	11 Mar 2021 14:45:49
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
User entered empty.	System	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
User entered empty.	System	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:51:31
User entered empty.	System	11 Mar 2021 14:45:49

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:33:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:33:50
Data point term sent to Coder	System	11 Mar 2021 14:46:51
User entered 'Docusate'	Erika Faust (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Left partial nephrectomy'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '100'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'twice daily (BID)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 06:58:10
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 18:09:28
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	24 Mar 2021 18:08:10
Signature has been broken.	David Diemert (b) (4)	24 Mar 2021 18:07:56
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4)	24 Mar 2021 18:07:56
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:00:39
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Yes (Y)'	Erika Faust (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 18:09:28
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 18:07:56
	(b) (4)	
User entered '01 Nov 2020' reason for change: New Information	David Diemert (b) (4)	24 Mar 2021 18:07:56
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	11 Mar 2021 17:56:18
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	11 Mar 2021 14:46:40
	(b) (4)	

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
User entered '2'	System	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
User entered 'I'	System	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:34
User entered '804 (804)'	System	11 Mar 2021 14:46:40

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:55:40
User signature succeeded.	David Diemert (b) (4) (b) (4)	11 Mar 2021 17:56:18
Data point term sent to Coder	System	11 Mar 2021 14:47:53
User entered 'Zofran (ondansetron)'	Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Left partial nephrectomy'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '4'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:21:53
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
User entered empty.	System	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
User entered empty.	System	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:21
User entered empty.	System	11 Mar 2021 14:47:29

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:09:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:04
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:14:55

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered '27 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	06 Nov 2020 16:15:20

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 18:28:09
	(b) (4)	
User entered 'Left PARTIAL NEPHRECTOMY'	Hannah Yellin (b) (4)	10 Mar 2021 18:28:09
reason for change: New Information	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
	(b) (4)	
User entered 'partial nephrectomy'	DeEnna Wedding (b) (4)	06 Nov 2020 16:15:20
	(b) (4)	

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	06 Nov 2020 16:15:45
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Nov 2020 16:15:20
User entered 'Adverse Event (AE)'	DeEnna Wedding (b) (4) (b) (4)	06 Nov 2020 16:15:20

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:08

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:01:58
User entered empty; reason for change Data Entry Error	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:15:45
User entered 'renal mass'	(b) (4)	
	DeEnna Wedding (b) (4)	06 Nov 2020 16:15:20
	(b) (4)	

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered '27 Oct 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:28:46

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered 'Left ureteral catheter placement'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:28:46

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered 'Adverse Event (AE)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:28:46

US3542199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:22:15
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:28:46

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered '09/Mar/2021 15:23'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:08

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'l'	(b) (4), (b) (6)	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered '10/Mar/2021 11:44'	(b) (4) System	10 Mar 2021 16:44:02

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:08

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 13:04:13
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:41:17
User entered 'l'	(b) (4), (b) (6)	10 Mar 2021 16:44:02

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered '11/Mar/2021 08:05'	(b) (4) System	11 Mar 2021 13:05:55

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:08

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:50:39
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:56:18
User entered 'l'	(b) (4), (b) (6)	11 Mar 2021 13:05:55

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 16:27:43
User entered '17/Mar/2021 10:50'	(b) (4) System	17 Mar 2021 14:50:35

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:08

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 16:27:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:50:39
User entered 'l'	(b) (4), (b) (6)	17 Mar 2021 14:50:35

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	29 Mar 2021 15:40:31
User entered '29/Mar/2021 06:33'	(b) (4) System	29 Mar 2021 13:33:42

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:08

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)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:42:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	29 Mar 2021 15:40:31
User entered 'l'	(b) (4), (b) (6)	29 Mar 2021 13:33:42

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'USA-US084-2021-MRNA-1273-P301000007'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Yes (Y)'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'No (N)'	System	09 Mar 2021 15:23:17

US3542199

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'David'	System	09 Mar 2021 15:23:17

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Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Diemert'	System	09 Mar 2021 15:23:17

US3542199

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Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '2300 Eye Street NW'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

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[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered 'Washington'	System	09 Mar 2021 15:23:17

US3542199

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:40
User entered '20037'	System	09 Mar 2021 15:23:17

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:43:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:20
User entered 'US'	(b) (4) System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	02 Apr 2021 14:42:23
User entered '5'	System	29 Mar 2021 13:33:42
User entered '4'	System	17 Mar 2021 14:50:35
User entered '3'	System	11 Mar 2021 13:05:55
User entered '2'	System	10 Mar 2021 16:44:02
User entered '1'	System	09 Mar 2021 15:23:47

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:09:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:56:34
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:16
User entered '02/Apr/2021 10:42'	(b) (4) System	02 Apr 2021 14:42:23

US3542199

Folder: SAE USA-US084-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

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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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:56:34
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:16
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 14:42:23