

US3542309 (Prod: George Washington University)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3542309

Form: Participant Creation

Data signed: (b) (4) 03 Oct 2020 15:47:00

Generated On: 10 Jun 2021 08:11:06

[Participant ID](#)

US3542309

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

US3542309

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Condition	ANEMIA (IRON DEFICIENCY)
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Condition	BENIGN BRAIN TUMOR
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Condition	UMBILICAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:33
Height (xxx.x)	67 in
Weight (xxx.x)	161 lb
BMI (xxx.x)	25.26889 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) 05 Mar 2021 15:02:34

Generated On: 10 Jun 2021 08:11:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 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: Childbearing Potential

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Date of assessment (dd MMM yyyy) 1 OCT 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2018

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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) 03 Oct 2020 15:47:11

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

What was the date of randomization? (dd MMM yyyy) 01 OCT 2020

What was the participant's randomization number? 115900

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) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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)	1 OCT 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:33
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 13:58
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:02:34

Generated On: 10 Jun 2021 08:11:06

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) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 13:16

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) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	12:48 (24 HR)
Collection date and time (derived)	1 OCT 2020 12:48

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:49	1 OCT 2020 12:49
Nasopharyngeal Swab 2	No		

US3542309

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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 08:11:06

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

01 OCT 2020 14:00

PC Open Date & Time

01 OCT 2020 13:36

PC Close Date & Time

01 OCT 2020 16:06

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	02 OCT 2020 01:51
PC Open Date & Time	01 OCT 2020 17:01
PC Close Date & Time	02 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 17:51

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 13:55

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 04 OCT 2020 13:25

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

93.2 °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

05 OCT 2020 19:00

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

93.2 °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

06 OCT 2020 20:21

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

93.2 °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

07 OCT 2020 23:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

01 OCT 2020 14:01

PC Open Date & Time

01 OCT 2020 13:36

PC Close Date & Time

01 OCT 2020 16:06

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

02 OCT 2020 08:23

PC Open Date & Time

01 OCT 2020 17:01

PC Close Date & Time

02 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 17:52

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 13:56

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 4
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	04 OCT 2020 13:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 19:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:21

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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	07 OCT 2020 23:34
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 14:01
PC Open Date & Time	01 OCT 2020 13:36
PC Close Date & Time	01 OCT 2020 16:06

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 01:52
PC Open Date & Time	01 OCT 2020 17:01
PC Close Date & Time	02 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

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)

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 17:52
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 ☒

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:56
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

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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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 13:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

53 of 2058

EAB) (1725)

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2058

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:22
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

57 of 2058

EAB) (1725)

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 23:35
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Oct 2020 13:10:57

Generated On: 10 Jun 2021 08:11:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542309

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 13:10:57

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 19:03:51

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 19:03:51

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

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)	28 OCT 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:04
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

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)	28 OCT 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:42
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3542309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

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) 28 OCT 2020

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

Treatment Date and Time (derived) 28 OCT 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

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	28 OCT 2020 10:15

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)			28 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:17	28 OCT 2020 10:17
Nasopharyngeal Swab 2	No		

US3542309

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 02:02:29

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 13:30

PC Open Date & Time

28 OCT 2020 11:32

PC Close Date & Time

28 OCT 2020 14:02

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 OCT 2020 14:57

PC Close Date & Time

29 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 OCT 2020 17:59
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

30 OCT 2020 15:49

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 22:37

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

93.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 19:07

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

94.2 °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

02 NOV 2020 14:23

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 18:03

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

28 OCT 2020 13:30

PC Open Date & Time

28 OCT 2020 11:32

PC Close Date & Time

28 OCT 2020 14:02

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 14:57

PC Close Date & Time

29 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

29 OCT 2020 17:59

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

30 OCT 2020 15:49

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 4
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	31 OCT 2020 22:37
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

01 NOV 2020 19:07

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 14:24

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

03 NOV 2020 18:03

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 13:31
PC Open Date & Time	28 OCT 2020 11:32
PC Close Date & Time	28 OCT 2020 14:02

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 14:57

PC Close Date & Time

29 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 ☒

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 18:00
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 15:50
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

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)

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 22:37
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

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)

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 19:08
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

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)

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 14:24
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 18:03
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 22:24:18

Generated On: 10 Jun 2021 08:11:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542309

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 22:24:18

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 22:24:18

Generated On: 10 Jun 2021 08:11:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542309

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 22:24:18

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Nov 2020 16:54:37

Generated On: 10 Jun 2021 08:11:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542309

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Nov 2020 16:54:37

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

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) _____

US3542309

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

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.

US3542309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3542309

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Patient Cloud Open Date & Time	05 DEC 2020 00:01
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Patient Cloud Close Date & Time	09 DEC 2020 23:59
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US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

12 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 138

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

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

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04 AUG 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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31 AUG 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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="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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

Date and time of submission

Patient Cloud Open Date & Time	22 OCT 2022 00:01
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Patient Cloud Close Date & Time	26 OCT 2022 23:59
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US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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 <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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

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

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3542309

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Jan 2021 19:26:12

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Jan 2021 19:26:12

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:19:26

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:19:26

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:19:26

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:19:26

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:19:32

Generated On: 10 Jun 2021 08:11:06

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments LEFT VOICEMAILS AT 9:22, 11:09, 14:39

If Contact Not Made, please provide Comments

US3542309

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:19:26

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 21 Apr 2021 02:50:43

Generated On: 10 Jun 2021 08:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Apr 2021 02:50:43

Generated On: 10 Jun 2021 08:11:06

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) _____

US3542309

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Apr 2021 02:50:43

Generated On: 10 Jun 2021 08:11:06

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.

US3542309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Apr 2021 02:50:43

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

11:09 (24 HR)

Collection date and time (derived)

19 APR 2021 11:09

US3542309

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 21 Apr 2021 02:50:43

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542309

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:11:06

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"/>

US3542309

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:11:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3542309

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

Date of updated informed consent (dd MMM yyyy) 15 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 15 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3542309

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	11:08 (24 HR)
Collection date and time (derived)	15 MAR 2021 11:08

US3542309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00 - 23:59)	11:10
Collection Date and Time (derived)	15 MAR 2021 11:10

US3542309

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Nov 2020 22:24:18

Generated On: 10 Jun 2021 08:11:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input 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)	29 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID

Adverse event

POSTERIOR SCALP
LACERATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID	
Adverse event	CHIARI MALFORMATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID	USA-US084-2020-MRNA-1273-P30 1000005
Adverse event	SUBARACHNOID HEMORRHAGE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 NOV 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)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 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 (4)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

PATIENT EXPERIENCED
SYNCOPE ON
13-NOV-2020. SHE REPORTS
FEELING "LIGHTEADEDNESS"
AND "ROOM-SPINNING" WHILE
STANDING AND PROCEEDED
TO HAVE A FALL. SHE
EXPERIENCED HEAD INJURY
AND LOSS OF CONSCIOUSNESS.
SUBJECT WAS TAKEN TO
NEARBY ED AND FOUND TO
HAVE ACUTE SUBARACHNOID
HEMORRHAGE ON CT BRAIN
WO CONTRAST. SARS-COV-2
TEST PERFORMED 13-NOV-20
WAS NOT DETECTED. CBC AND
CMP WERE PERFORMED AND
RELATIVELY UNREMARKABLE.
TROPONIN WAS NEGATIVE.
ETHANOL LEVEL WAS
NEGATIVE. EKG SHOWED NSR.
US CAROTID DUPLEX
BILATERAL WAS NORMAL. TTE
WITH DOPPLER SHOWED
NORMAL LEFT AND RIGHT
VENTRICULAR CHAMBER SIZE
AND FUNCTION. NO EVIDENCE
OF SIGNIFICANT VALVULAR
DYSFUNCTION. EF 65-70%.
NEUROLOGY AND
NEUROSURGERY WERE
CONSULTED AND SUBJECT
WAS ADMITTED TO
NEUROLOGY SERVICE FOR
OBSERVATION. SUBJECT ALSO

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

EXPERIENCED POSTERIOR
SCALP LACERATION AS
RESULT OF FALL. IN ADDITION,
CT HEAD SHOWED CHIARI
MALFORMATION (LIKELY
CONGENITAL). SUBJECT WAS
DISCHARGED ON 15-NOV-2020
AND IS SCHEDULED TO F/U
WITH NEUROLOGY AND PCP.

PMH INCLUDES IRON
DEFICIENCY ANEMIA,
ENVIRONMENTAL ALLERGIES,
BENIGN BRAIN TUMOR (1999),
UMBILICAL HERNIA REPAIR
(1966) AND HYSTERECTOMY
(2018).

PARTICIPANT HAD REPEAT MRI
ON 11-DEC-20 WHICH SHOWED
RESOLUTION OF SAH.

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

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID	
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 NOV 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)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID	
Adverse event	INSOMNIA
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)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

AEID

Adverse event

SHINGLES (LEFT FLANK)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Mar 2021 20:19:45

Generated On: 10 Jun 2021 08:11:06

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

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Oct 2020 15:47:11

Generated On: 10 Jun 2021 08:11:06

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

Yes ☒

No ☐

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

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES (ENVIRONMENTAL)

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 (1)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	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)		29 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication LIDOCAINE (1%)

Prophylaxis Yes ☐
No ☒

Indication POSTERIOR SCALP
LACERATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="radio"/>
	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	INTRADERMAL	
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROHYLAXIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication TDAP VACCINE

Prophylaxis Yes ☒
No ☐

Indication TETANUS 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication LEVETIRACETAM

Prophylaxis Yes ☐
No ☒

Indication SUBARACHNOID
HEMORRHAGE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 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)		2
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 (7)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SUBARACHNOID
HEMORRHAGE

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

Q6H PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SUBARACHNOID
HEMORRHAGE

Dose per administration 800

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

Q8H PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication	DERMABOND
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POSTERIOR SCALP LACERATION
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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

ONCE EVERY EVENING AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:07:27

Generated On: 10 Jun 2021 08:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Nov 2020 16:54:24

Generated On: 10 Jun 2021 08:11:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Feb 2021 01:55:01

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	POSTERIOR SCALP LACERATION REPAIR	Adverse Event	
13 NOV 2020	CT HEAD & CERVICAL SPINE	Adverse Event	
14 NOV 2020	CAROTID ULTRASOUND, BILATERAL	Adverse Event	
11 DEC 2020	MRI BRAIN	Adverse Event	
15 NOV 2020	TRANSTHORACIC ECHOCARDIOGRAM WITH DOPPLER	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:11:06

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:11:06

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 ☐

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

SAEID	USA-US084-2020-MRNA-1273-P301000005
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)	2

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

SAEID	USA-US084-2020-MRNA-1273-P301000005
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)	2
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Dec 2020 16:21:07

Generated On: 10 Jun 2021 08:11:06

SAEID	USA-US084-2020-MRNA-1273-P301000005
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)	2
Date of submission (Pre-filled from custom function)	17/DEC/2020 19:15
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

US3542309 (Prod: George Washington University)

US3542309

Form: Participant Creation

Generated On: 10 Jun 2021 08:11:06

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:09:25
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'US3542309'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:27:42

US3542309

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:30:46

US3542309

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:27:44

US3542309

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:30:46

US3542309

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'SCRN'	System	01 Oct 2020 16:30:46

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:27:45

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '57'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'YEARS'	System	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '57'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Female (F)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Oct 2020'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '2020'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Amendment 3 (3)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:27:44

US3542309

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'l'	System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:11:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:19

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Anemia iron deficiency - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:13:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:13:55
Data point term sent to Coder	System	02 Oct 2020 17:36:36
User entered 'Anemia (iron deficiency)'	Erika Faust (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 1970'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 1970'	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1970'	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:16:54
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 02:27:44
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 17:38:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:38:51
Data point term sent to Coder	System	02 Oct 2020 17:37:38
User entered 'Hysterectomy'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 2018'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 2018'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms benign, HLT: Nervous system neoplasms benign NEC, PT: Brain neoplasm benign, LLT: Brain neoplasm benign - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:38:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:38:51
Data point term sent to Coder	System	02 Oct 2020 17:37:38
User entered 'Benign brain tumor'	Erika Faust (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 1999'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 1999'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:39:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:39:52
Data point term sent to Coder	System	02 Oct 2020 17:38:39
User entered 'Umbilical hernia repair'	Erika Faust (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 1966'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 1966'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:39:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:39:52
Data point term sent to Coder	System	02 Oct 2020 17:38:39
User entered 'Allergies (environmental)'	Erika Faust (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 2018'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'Jan 2018'	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '2018'	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '12:33'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '1 Oct 2020 12:33'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '67' in	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:57
DataPoint set to visible.	(b) (4) System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '161' lb	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:57
DataPoint set to visible.	(b) (4) System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '25.26889'	System	02 Oct 2020 17:39:57
DataPoint set to visible.	System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'kg/m2'	System	02 Oct 2020 17:39:57
DataPoint set to visible.	System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'bpm'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'breaths/min'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'mmHg'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'mmHg'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17

US3542309

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:02:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:39:24
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:39:24
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	02 Oct 2020 17:35:40
	(b) (4)	

US3542309

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:02:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:39:24
User entered '01 Oct 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:39:24
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	02 Oct 2020 17:35:40
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'UN UNK 2018'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:11:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:29

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:29

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[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 08:19:43
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:29

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User entered 'VISIT1'	System	01 Oct 2020 17:25:29

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:32:42

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '115900'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:32:42

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:32:42

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:32

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:32

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:35:32

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:32

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:32

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:35:32
DataPoint set to visible.	(b) (4) System	01 Oct 2020 16:31:04

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '12:33'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered '1 Oct 2020 12:33'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '98.0' F	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '55'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'bpm'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '17'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'breaths/min'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '132'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '82'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '13:58'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered '1 Oct 2020 13:58'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '97.9' F	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '56'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'bpm'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'breaths/min'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '136'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '85'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:02:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:40:10
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:40:10
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4)	
	Erika Faust (b) (4)	02 Oct 2020 17:35:50
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:02:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:40:10
User entered empty; reason for change New Information	(b) (4)	
	Erika Faust (b) (4)	02 Mar 2021 19:40:10
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4)	
	Erika Faust (b) (4)	02 Oct 2020 17:35:50
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '13:16'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered '1 Oct 2020 13:16'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) Elissa Malkin (b) (4)	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'ONCE'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:41:44

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:41:44

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '12:48'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:44

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User entered '1 Oct 2020 12:48'	System	02 Oct 2020 17:41:44

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 01Oct2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:41:40
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 01Oct2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Cannot be resolved until PPD lab addresses and resolves issue.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	23 Oct 2020 16:51:22
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 01Oct2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:33:46
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:47:11
User entered '1 Oct 2020'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '12:49'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User entered '1 Oct 2020 12:49'	System	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User entered empty.	System	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:34:56

US3542309

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'I'	System	02 Oct 2020 17:34:56

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7ad12f84-7416-4365-9c22-432ac61babbd' User entered 'Yes (Y)'	System	01 Oct 2020 18:00:38
	System	01 Oct 2020 18:00:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:12', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7ad12f84-7416-4365-9c22-432ac61babbd' User entered '97.9'	System	01 Oct 2020 18:00:38
	System	01 Oct 2020 18:00:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:21', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7ad12f84-7416-4365-9c22-432ac61babbd' User entered 'No (N)'	System	01 Oct 2020 18:00:38
	System	01 Oct 2020 18:00:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7ad12f84-7416-4365-9c22-432ac61babbd' User entered '01 Oct 2020 14:00'	System	01 Oct 2020 18:00:38
	System	01 Oct 2020 18:00:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 13:36'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 16:06'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:01', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '64dc9ab5-1064-42a1-bc4d-9c2dee7cc2e3' User entered 'Yes (Y)'	System	02 Oct 2020 05:51:09
	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:50:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '64dc9ab5-1064-42a1-bc4d-9c2dee7cc2e3' User entered '98.1'	System	02 Oct 2020 05:51:09
	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:50:31', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '64dc9ab5-1064-42a1-bc4d-9c2dee7cc2e3'	System	02 Oct 2020 05:51:09
User entered 'No (N)'	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '64dc9ab5-1064-42a1-bc4d-9c2dee7cc2e3' User entered '02 Oct 2020 01:51'	System	02 Oct 2020 05:51:09
	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 17:01'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 2'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:19', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e474ab1b-9d9d-466e-9b80-e356f378c7ab' User entered 'Yes (Y)'	System	02 Oct 2020 21:51:40
	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:28', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e474ab1b-9d9d-466e-9b80-e356f378c7ab' User entered '96.3'	System	02 Oct 2020 21:51:40
	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e474ab1b-9d9d-466e-9b80-e356f378c7ab' User entered 'No (N)'	System	02 Oct 2020 21:51:40
	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e474ab1b-9d9d-466e-9b80-e356f378c7ab' User entered '02 Oct 2020 17:51'	System	02 Oct 2020 21:51:40
	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 3'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:20', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ba28c8b-adff-42ff-9278-39f5c50335f9' User entered 'Yes (Y)'	System	03 Oct 2020 17:55:38
	System	03 Oct 2020 17:55:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ba28c8b-adff-42ff-9278-39f5c50335f9' User entered '96.3'	System	03 Oct 2020 17:55:38
	System	03 Oct 2020 17:55:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ba28c8b-adff-42ff-9278-39f5c50335f9'	System	03 Oct 2020 17:55:38
User entered 'No (N)'	System	03 Oct 2020 17:55:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ba28c8b-adff-42ff-9278-39f5c50335f9' User entered '03 Oct 2020 13:55'	System	03 Oct 2020 17:55:38
	System	03 Oct 2020 17:55:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 4'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:25:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5736d691-03fd-420c-b7e5-5ce5492b760d' User entered 'No (N)'	System	04 Oct 2020 17:26:00
	System	04 Oct 2020 17:26:00

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:25:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5736d691-03fd-420c-b7e5-5ce5492b760d' User entered 'No (N)'	System	04 Oct 2020 17:26:00
	System	04 Oct 2020 17:26:00

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:25:58', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5736d691-03fd-420c-b7e5-5ce5492b760d' User entered '04 Oct 2020 13:25'	System	04 Oct 2020 17:26:00
	System	04 Oct 2020 17:26:00

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 5'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:00:36', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ecb8deb-422b-4aba-8021-1bf20a304090' User entered 'Yes (Y)'	System	05 Oct 2020 23:01:04
	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:00:45', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ecb8deb-422b-4aba-8021-1bf20a304090' User entered '93.2'	System	05 Oct 2020 23:01:04
	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:00:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ecb8deb-422b-4aba-8021-1bf20a304090' User entered 'No (N)'	System	05 Oct 2020 23:01:04
	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:00:59', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6ecb8deb-422b-4aba-8021-1bf20a304090' User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:01:04
	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 6'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:08', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '9a7ba086-1a3c-4773-a43d-1d8ba80e6fa7' User entered 'Yes (Y)'	System	07 Oct 2020 00:21:28
	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:17', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '9a7ba086-1a3c-4773-a43d-1d8ba80e6fa7' User entered '93.2'	System	07 Oct 2020 00:21:28
	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:20', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '9a7ba086-1a3c-4773-a43d-1d8ba80e6fa7'	System	07 Oct 2020 00:21:28
User entered 'No (N)'	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:25', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '9a7ba086-1a3c-4773-a43d-1d8ba80e6fa7' User entered '06 Oct 2020 20:21'	System	07 Oct 2020 00:21:28
	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 7'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:25', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7a31f337-8038-4f37-8cf3-d11dce25219a' User entered 'Yes (Y)'	System	08 Oct 2020 03:34:44
	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7a31f337-8038-4f37-8cf3-d11dce25219a' User entered '93.2'	System	08 Oct 2020 03:34:44
	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7a31f337-8038-4f37-8cf3-d11dce25219a' User entered 'No (N)'	System	08 Oct 2020 03:34:44
	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '7a31f337-8038-4f37-8cf3-d11dce25219a' User entered '07 Oct 2020 23:34'	System	08 Oct 2020 03:34:44
	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'f310e5f2-e2b0-473a-9d88-9b0af67fee3a' User entered 'None (1)'	System	01 Oct 2020 18:01:09
	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:44', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'f310e5f2-e2b0-473a-9d88-9b0af67fee3a' User entered 'No (N)'	System	01 Oct 2020 18:01:09
	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:49', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'f310e5f2-e2b0-473a-9d88-9b0af67fee3a' User entered 'No (N)'	System	01 Oct 2020 18:01:09
	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:00:54', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'f310e5f2-e2b0-473a-9d88-9b0af67fee3a' User entered 'None (1)'	System	01 Oct 2020 18:01:09
	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:00', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'f310e5f2-e2b0-473a-9d88-9b0af67fee3a' User entered '01 Oct 2020 14:01'	System	01 Oct 2020 18:01:09
	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 13:36'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 16:06'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T08:22:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'a2ece8ae-9200-4162-89bd-be3e64c2a0ab' User entered 'None (1)'	System	02 Oct 2020 12:23:11
	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T08:22:45', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'a2ece8ae-9200-4162-89bd-be3e64c2a0ab' User entered 'No (N)'	System	02 Oct 2020 12:23:11
	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T08:22:51', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'a2ece8ae-9200-4162-89bd-be3e64c2a0ab' User entered 'No (N)'	System	02 Oct 2020 12:23:11
	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T08:22:59', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'a2ece8ae-9200-4162-89bd-be3e64c2a0ab' User entered 'None (1)'	System	02 Oct 2020 12:23:11
	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T08:23:08', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'a2ece8ae-9200-4162-89bd-be3e64c2a0ab' User entered '02 Oct 2020 08:23'	System	02 Oct 2020 12:23:11
	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 17:01'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 2'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:54', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '05396503-0ccd-4bc0-8e11-8f9a2a0b720a' User entered 'None (1)'	System	02 Oct 2020 21:52:09
	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:51:58', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '05396503-0ccd-4bc0-8e11-8f9a2a0b720a' User entered 'No (N)'	System	02 Oct 2020 21:52:09
	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:01', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '05396503-0ccd-4bc0-8e11-8f9a2a0b720a' User entered 'No (N)'	System	02 Oct 2020 21:52:09
	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '05396503-0ccd-4bc0-8e11-8f9a2a0b720a' User entered 'None (1)'	System	02 Oct 2020 21:52:09
	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:07', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '05396503-0ccd-4bc0-8e11-8f9a2a0b720a' User entered '02 Oct 2020 17:52'	System	02 Oct 2020 21:52:09
	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 3'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:46', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6f97f4d6-96fa-4b6f-b422-07a9b02a4412'	System	03 Oct 2020 17:56:08
User entered 'None (1)'	System	03 Oct 2020 17:56:08

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6f97f4d6-96fa-4b6f-b422-07a9b02a4412'	System	03 Oct 2020 17:56:08
User entered 'No (N)'	System	03 Oct 2020 17:56:08

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:55:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6f97f4d6-96fa-4b6f-b422-07a9b02a4412'	System	03 Oct 2020 17:56:08
User entered 'No (N)'	System	03 Oct 2020 17:56:08

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:03', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6f97f4d6-96fa-4b6f-b422-07a9b02a4412'	System	03 Oct 2020 17:56:08
User entered 'None (1)'	System	03 Oct 2020 17:56:08

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:06', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '6f97f4d6-96fa-4b6f-b422-07a9b02a4412'	System	03 Oct 2020 17:56:08
User entered '03 Oct 2020 13:56'	System	03 Oct 2020 17:56:08

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 4'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1669ce96-1dbb-4650-a70f-d0c62420772c' User entered 'None (1)'	System	04 Oct 2020 17:26:18
	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:05', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1669ce96-1dbb-4650-a70f-d0c62420772c' User entered 'No (N)'	System	04 Oct 2020 17:26:18
	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:08', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1669ce96-1dbb-4650-a70f-d0c62420772c' User entered 'No (N)'	System	04 Oct 2020 17:26:18
	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:13', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1669ce96-1dbb-4650-a70f-d0c62420772c' User entered 'None (1)'	System	04 Oct 2020 17:26:18
	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:16', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1669ce96-1dbb-4650-a70f-d0c62420772c' User entered '04 Oct 2020 13:26'	System	04 Oct 2020 17:26:18
	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 5'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78f15199-e76b-4b05-80d3-0b6390448b88'	System	05 Oct 2020 23:01:19
User entered 'None (1)'	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:07', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78f15199-e76b-4b05-80d3-0b6390448b88' User entered 'No (N)'	System	05 Oct 2020 23:01:19
	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:10', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78f15199-e76b-4b05-80d3-0b6390448b88' User entered 'No (N)'	System	05 Oct 2020 23:01:19
	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78f15199-e76b-4b05-80d3-0b6390448b88'	System	05 Oct 2020 23:01:19
User entered 'None (1)'	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:17', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78f15199-e76b-4b05-80d3-0b6390448b88' User entered '05 Oct 2020 19:01'	System	05 Oct 2020 23:01:19
	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 6'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78cb1ab4-f862-4067-90b2-f0b1be5af6ec'	System	07 Oct 2020 00:21:44
User entered 'None (1)'	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78cb1ab4-f862-4067-90b2-f0b1be5af6ec'	System	07 Oct 2020 00:21:44
User entered 'No (N)'	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78cb1ab4-f862-4067-90b2-f0b1be5af6ec' User entered 'No (N)'	System	07 Oct 2020 00:21:44
	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78cb1ab4-f862-4067-90b2-f0b1be5af6ec'	System	07 Oct 2020 00:21:44
User entered 'None (1)'	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '78cb1ab4-f862-4067-90b2-f0b1be5af6ec' User entered '06 Oct 2020 20:21'	System	07 Oct 2020 00:21:44
	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 7'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:46', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '735b90ec-d2c5-4bfd-882d-773afb0b9f37'	System	08 Oct 2020 03:35:00
User entered 'None (1)'	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '735b90ec-d2c5-4bfd-882d-773afb0b9f37' User entered 'No (N)'	System	08 Oct 2020 03:35:00
	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '735b90ec-d2c5-4bfd-882d-773afb0b9f37'	System	08 Oct 2020 03:35:00
User entered 'No (N)'	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:53', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '735b90ec-d2c5-4bfd-882d-773afb0b9f37'	System	08 Oct 2020 03:35:00
User entered 'None (1)'	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:34:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '735b90ec-d2c5-4bfd-882d-773afb0b9f37' User entered '07 Oct 2020 23:34'	System	08 Oct 2020 03:35:00
	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:09', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:18', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:26', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'None (0)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered 'No (N)'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-01T14:01:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b576f37c-19fb-4c75-bc94-718edd2e8821' User entered '01 Oct 2020 14:01'	System	01 Oct 2020 18:01:41
	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 13:36'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 16:06'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:52:16', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:44', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:48', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:51:51', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'None (0)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:52:01', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered 'No (N)'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T01:52:20', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '1b4f2e18-b7e2-4d86-984c-16a8ffc48384' User entered '02 Oct 2020 01:52'	System	02 Oct 2020 05:52:22
	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Oct 2020 17:01'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 2'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:12', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:19', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:25', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'None (0)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered 'No (N)'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-02T17:52:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '75926f85-95c8-4017-a5a6-ccd66ef33567' User entered '02 Oct 2020 17:52'	System	02 Oct 2020 21:52:36
	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 3'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:14', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:17', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:21', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:25', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'None (0)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered 'No (N)'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-03T13:56:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '52f1451f-11c2-4ff9-997e-1a92000449eb' User entered '03 Oct 2020 13:56'	System	03 Oct 2020 17:56:39
	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 4'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:20', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:23', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:24', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:31', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:33', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'None (0)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered 'No (N)'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-04T13:26:40', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '30488ec8-daa5-4d3c-84d9-b8b10eed6c60' User entered '04 Oct 2020 13:26'	System	04 Oct 2020 17:26:43
	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 5'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:24', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:29', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'None (0)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:35', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered 'No (N)'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-05T19:01:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '50e1b650-9cc0-4517-b2f2-471fc06fc8be' User entered '05 Oct 2020 19:01'	System	05 Oct 2020 23:01:41
	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 6'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:47', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:49', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:54', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:56', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'None (0)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:21:59', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered 'No (N)'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-06T20:22:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3d202000-1dcc-4ada-b53c-37b156c87e39' User entered '06 Oct 2020 20:22'	System	07 Oct 2020 00:22:05
	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	01 Oct 2020 17:25:51
User entered 'Day 7'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:00', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:01', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:03', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:06', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:07', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'None (0)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:09', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered 'No (N)'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-07T23:35:14', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '47ef6f27-f9d3-408c-afa2-12200b532830' User entered '07 Oct 2020 23:35'	System	08 Oct 2020 03:35:18
	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:25:51

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:25:51

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Oct 2020 19:36:44

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
User entered '9 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Oct 2020 19:36:44

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Oct 2020 19:36:44

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
User entered empty.	(b) (4) Erika Faust (b) (4)	12 Oct 2020 19:36:44

US3542309

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	12 Oct 2020 19:36:50

US3542309

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'l'	System	12 Oct 2020 19:36:50

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:51:31

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:03:51
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:51:31

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:51:31

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:51:31

US3542309

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:51:37

US3542309

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'l'	System	20 Oct 2020 17:51:37

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	26 Oct 2020 18:38:43

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '23 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	26 Oct 2020 18:38:43

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	26 Oct 2020 18:38:43

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) Erika Faust (b) (4)	26 Oct 2020 18:38:43

US3542309

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	26 Oct 2020 18:38:49

US3542309

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'I'	System	26 Oct 2020 18:38:49

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:02

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:02

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[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 08:19:43
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:02

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User entered 'VISIT2'	System	29 Oct 2020 16:28:02

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '10:04'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered '28 Oct 2020 10:04'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '73'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'bpm'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '14'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'breaths/min'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '137'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '90'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '11:42'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered '28 Oct 2020 11:42'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '53'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'bpm'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '14'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'breaths/min'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '129'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '78'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered 'mmHg'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:30:11

US3542309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:30:11

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'MRNA-1273 OR PLACEBO'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '11:12'	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered '28 Oct 2020 11:12'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'ONCE'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:57
User entered 'INTRAMUSCULAR'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:00

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:00

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '10:15'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:00

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User entered '28 Oct 2020 10:15'	System	29 Oct 2020 16:31:00

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '10:17'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User entered '28 Oct 2020 10:17'	System	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:13:59
User entered empty.	System	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:31:35

US3542309

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'I'	System	29 Oct 2020 16:31:35

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2dab1b73-3550-4cda-9558-70125c357779' User entered 'Yes (Y)'	System	28 Oct 2020 17:30:38
	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:18', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2dab1b73-3550-4cda-9558-70125c357779' User entered '96.2'	System	28 Oct 2020 17:30:38
	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:22', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2dab1b73-3550-4cda-9558-70125c357779'	System	28 Oct 2020 17:30:38
User entered 'No (N)'	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:24', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2dab1b73-3550-4cda-9558-70125c357779' User entered '28 Oct 2020 13:30'	System	28 Oct 2020 17:30:38
	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 11:32'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:02'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:57'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 2'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:58:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a' User entered 'Yes (Y)'	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:58:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a' User entered '100.4'	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:58:59', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a'	System	29 Oct 2020 21:59:22
User entered 'Yes (Y)'	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and medication was added to the concomitant medication page.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 09:40:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Erika Faust (b) (4)	05 Nov 2020 16:30:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:16', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a'	(b) (4)	
User entered '1'	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:16', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a' User entered '0'	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:19', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '97e4d1a9-2ad3-4e6c-8960-386adc9e7c7a' User entered '29 Oct 2020 17:59'	System	29 Oct 2020 21:59:22
	System	29 Oct 2020 21:59:22

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 3'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:33', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'fb2e5c45-3447-4ab0-915b-f6b4a00d472b' User entered 'Yes (Y)'	System	30 Oct 2020 19:49:49
	System	30 Oct 2020 19:49:49

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'fb2e5c45-3447-4ab0-915b-f6b4a00d472b' User entered '97.2'	System	30 Oct 2020 19:49:49
	System	30 Oct 2020 19:49:49

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:43', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'fb2e5c45-3447-4ab0-915b-f6b4a00d472b' User entered 'No (N)'	System	30 Oct 2020 19:49:49
	System	30 Oct 2020 19:49:49

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:45', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'fb2e5c45-3447-4ab0-915b-f6b4a00d472b' User entered '30 Oct 2020 15:49'	System	30 Oct 2020 19:49:49
	System	30 Oct 2020 19:49:49

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 4'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:13', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'd2325a9d-806d-4d58-89bf-698ec619d58f' User entered 'Yes (Y)'	System	01 Nov 2020 02:37:33
	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:24', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'd2325a9d-806d-4d58-89bf-698ec619d58f' User entered '96.2'	System	01 Nov 2020 02:37:33
	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:28', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'd2325a9d-806d-4d58-89bf-698ec619d58f' User entered 'No (N)'	System	01 Nov 2020 02:37:33
	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'd2325a9d-806d-4d58-89bf-698ec619d58f' User entered '31 Oct 2020 22:37'	System	01 Nov 2020 02:37:33
	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 5'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5d4c07f7-ce01-4924-ba6d-0509ffb49659' User entered 'Yes (Y)'	System	02 Nov 2020 00:07:38
	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:29', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5d4c07f7-ce01-4924-ba6d-0509ffb49659' User entered '93.2'	System	02 Nov 2020 00:07:38
	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:33', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5d4c07f7-ce01-4924-ba6d-0509ffb49659'	System	02 Nov 2020 00:07:38
User entered 'No (N)'	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:35', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '5d4c07f7-ce01-4924-ba6d-0509ffb49659' User entered '01 Nov 2020 19:07'	System	02 Nov 2020 00:07:38
	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 6'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:18', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2b3d1854-0d10-42e6-b106-65649191f383' User entered 'Yes (Y)'	System	02 Nov 2020 19:23:51
	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2b3d1854-0d10-42e6-b106-65649191f383' User entered '94.2'	System	02 Nov 2020 19:23:51
	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:47', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2b3d1854-0d10-42e6-b106-65649191f383'	System	02 Nov 2020 19:23:51
User entered 'No (N)'	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '2b3d1854-0d10-42e6-b106-65649191f383' User entered '02 Nov 2020 14:23'	System	02 Nov 2020 19:23:51
	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 7'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0dfd7193-0195-446c-9555-06ecbfabec8f' User entered 'Yes (Y)'	System	03 Nov 2020 23:03:17
	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:09', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0dfd7193-0195-446c-9555-06ecbfabec8f' User entered '96.2'	System	03 Nov 2020 23:03:17
	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:12', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0dfd7193-0195-446c-9555-06ecbfabec8f' User entered 'No (N)'	System	03 Nov 2020 23:03:17
	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:14', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0dfd7193-0195-446c-9555-06ecbfabec8f' User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:17
	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '245b781c-6f5a-4b09-ad03-8278bb936451' User entered 'None (1)'	System	28 Oct 2020 17:30:47
	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '245b781c-6f5a-4b09-ad03-8278bb936451' User entered 'No (N)'	System	28 Oct 2020 17:30:47
	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:37', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '245b781c-6f5a-4b09-ad03-8278bb936451' User entered 'No (N)'	System	28 Oct 2020 17:30:47
	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '245b781c-6f5a-4b09-ad03-8278bb936451' User entered 'None (1)'	System	28 Oct 2020 17:30:47
	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '245b781c-6f5a-4b09-ad03-8278bb936451' User entered '28 Oct 2020 13:30'	System	28 Oct 2020 17:30:47
	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 11:32'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:02'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:57'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 2'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:23', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '15f43a75-d9fb-427a-8e1c-54518e581777'	System	29 Oct 2020 21:59:39
User entered 'None (1)'	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '15f43a75-d9fb-427a-8e1c-54518e581777' User entered 'No (N)'	System	29 Oct 2020 21:59:39
	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:30', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '15f43a75-d9fb-427a-8e1c-54518e581777' User entered 'No (N)'	System	29 Oct 2020 21:59:39
	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '15f43a75-d9fb-427a-8e1c-54518e581777'	System	29 Oct 2020 21:59:39
User entered 'None (1)'	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '15f43a75-d9fb-427a-8e1c-54518e581777' User entered '29 Oct 2020 17:59'	System	29 Oct 2020 21:59:39
	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 3'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:49', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'bfc6c01a-d96a-4286-bd85-417a5878c0ef' User entered 'None (1)'	System	30 Oct 2020 19:49:59
	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'bfc6c01a-d96a-4286-bd85-417a5878c0ef' User entered 'No (N)'	System	30 Oct 2020 19:49:59
	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:53', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'bfc6c01a-d96a-4286-bd85-417a5878c0ef' User entered 'No (N)'	System	30 Oct 2020 19:49:59
	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'bfc6c01a-d96a-4286-bd85-417a5878c0ef' User entered 'None (1)'	System	30 Oct 2020 19:49:59
	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:49:57', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'bfc6c01a-d96a-4286-bd85-417a5878c0ef' User entered '30 Oct 2020 15:49'	System	30 Oct 2020 19:49:59
	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 4'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:33', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '4092b7b6-38fe-4e0a-9259-bb1bafc6e535'	System	01 Nov 2020 02:37:45
User entered 'None (1)'	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:36', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '4092b7b6-38fe-4e0a-9259-bb1bafc6e535'	System	01 Nov 2020 02:37:45
User entered 'No (N)'	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '4092b7b6-38fe-4e0a-9259-bb1bafc6e535' User entered 'No (N)'	System	01 Nov 2020 02:37:45
	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:39', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '4092b7b6-38fe-4e0a-9259-bb1bafc6e535'	System	01 Nov 2020 02:37:45
User entered 'None (1)'	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '4092b7b6-38fe-4e0a-9259-bb1bafc6e535' User entered '31 Oct 2020 22:37'	System	01 Nov 2020 02:37:45
	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 5'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '637ebe35-4346-431d-ab29-48ae30e1c74d' User entered 'None (1)'	System	02 Nov 2020 00:07:53
	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:41', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '637ebe35-4346-431d-ab29-48ae30e1c74d' User entered 'No (N)'	System	02 Nov 2020 00:07:53
	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:43', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '637ebe35-4346-431d-ab29-48ae30e1c74d' User entered 'No (N)'	System	02 Nov 2020 00:07:53
	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:45', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '637ebe35-4346-431d-ab29-48ae30e1c74d' User entered 'None (1)'	System	02 Nov 2020 00:07:53
	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:47', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '637ebe35-4346-431d-ab29-48ae30e1c74d' User entered '01 Nov 2020 19:07'	System	02 Nov 2020 00:07:53
	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 6'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:53', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0d2870cf-a00e-4a0a-b401-1b3cd6cf8123' User entered 'None (1)'	System	02 Nov 2020 19:24:11
	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:23:58', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0d2870cf-a00e-4a0a-b401-1b3cd6cf8123' User entered 'No (N)'	System	02 Nov 2020 19:24:11
	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:00', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0d2870cf-a00e-4a0a-b401-1b3cd6cf8123' User entered 'No (N)'	System	02 Nov 2020 19:24:11
	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0d2870cf-a00e-4a0a-b401-1b3cd6cf8123' User entered 'None (1)'	System	02 Nov 2020 19:24:11
	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:05', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0d2870cf-a00e-4a0a-b401-1b3cd6cf8123' User entered '02 Nov 2020 14:24'	System	02 Nov 2020 19:24:11
	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 7'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:18', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3c70d3b7-aa24-4c6f-85b2-c0728782e716' User entered 'None (1)'	System	03 Nov 2020 23:03:30
	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:21', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3c70d3b7-aa24-4c6f-85b2-c0728782e716' User entered 'No (N)'	System	03 Nov 2020 23:03:30
	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:23', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3c70d3b7-aa24-4c6f-85b2-c0728782e716' User entered 'No (N)'	System	03 Nov 2020 23:03:30
	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:25', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3c70d3b7-aa24-4c6f-85b2-c0728782e716' User entered 'None (1)'	System	03 Nov 2020 23:03:30
	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:27', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '3c70d3b7-aa24-4c6f-85b2-c0728782e716' User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:30
	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:45', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:47', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:49', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:51', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:54', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'None (0)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:30:57', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered 'No (N)'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-28T13:31:00', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '0494f1ed-68d3-4984-b55b-7ba3052e3068' User entered '28 Oct 2020 13:31'	System	28 Oct 2020 17:31:09
	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 11:32'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:02'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '28 Oct 2020 14:57'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 2'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:43', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:46', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:48', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:53', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'None (0)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T17:59:57', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered 'No (N)'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-29T18:00:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'b689d777-5f2c-4a49-8121-a9f13a09b88e' User entered '29 Oct 2020 18:00'	System	29 Oct 2020 22:00:12
	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 3'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:01', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:03', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:05', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:06', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:08', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:11', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'None (0)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:13', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered 'No (N)'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-30T15:50:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '42dd76dd-2115-4981-b78e-e4f4150cf82e' User entered '30 Oct 2020 15:50'	System	30 Oct 2020 19:50:20
	System	30 Oct 2020 19:50:20

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 4'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:46', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:47', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:48', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:50', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:52', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'None (0)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:57', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered 'No (N)'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-10-31T22:37:59', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: '82aa21af-5b3c-4830-bc87-8ab4d7e8c424' User entered '31 Oct 2020 22:37'	System	01 Nov 2020 02:38:03
	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 5'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:51', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:53', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:55', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:57', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:07:58', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:08:00', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'None (0)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:08:02', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered 'No (N)'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-01T19:08:04', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'e9c6a4b2-70cc-4d85-9dfe-211c60e5797e' User entered '01 Nov 2020 19:08'	System	02 Nov 2020 00:08:08
	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 6'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:08', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:10', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:12', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:14', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:15', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:17', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'None (0)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:20', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered 'No (N)'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-02T14:24:23', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'dedcf1d7-2179-4e4e-ad95-3613b2ae1f68' User entered '02 Nov 2020 14:24'	System	02 Nov 2020 19:24:26
	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
Data entry locked.	System	28 Oct 2020 15:15:40
User entered 'Day 7'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:31', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55'	System	03 Nov 2020 23:03:45
User entered 'None (0)'	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:32', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'None (0)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:34', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'None (0)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:35', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'None (0)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:36', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'None (0)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:38', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'None (0)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

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 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:40', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered 'No (N)'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F197C75A-92C2-455C-864F-B841C174D12E)', Time: '2020-11-03T18:03:42', User OID: 'PatientReportedOutcome (US3542309)', ODM File OID: 'ce3dd9f6-19d7-4408-ad97-f897dd458c55' User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:45
	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:15:40

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:10:52
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:15:40

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '4 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	05 Nov 2020 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4)	05 Nov 2020 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:25:43

US3542309

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'I'	System	05 Nov 2020 16:25:43

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:58:05

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:58:05

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:58:05

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:58:05

US3542309

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:58:13

US3542309

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'l'	System	12 Nov 2020 17:58:13

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:37
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:29:24

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:37
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	18 Nov 2020 20:29:37
answered by data change (Site from System).		
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	18 Nov 2020 20:29:37
User entered '18 Nov 2020' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:37
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '13 Nov 2020'	System	18 Nov 2020 20:29:24
	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:24
	(b) (4)	

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:29:24

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:37
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:29:24

US3542309

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:37
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:29:43

US3542309

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'l'	System	18 Nov 2020 20:29:43

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:44:37

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:44:37

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[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 08:19:43
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:44:37

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:19:43
User entered 'VISIT3'	System	18 Dec 2020 15:44:37

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered empty.	System	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered empty.	System	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered empty.	System	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered empty.	System	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55
User entered empty.	System	18 Dec 2020 15:45:04

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:55

US3542309

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 15:45:12

US3542309

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:12

US3542309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:27

US3542309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:45:27

US3542309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 15:45:27

US3542309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:30
User entered empty.	System	18 Dec 2020 15:45:27

US3542309

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:50:32

US3542309

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'I'	System	18 Dec 2020 15:50:32

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:27:10

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:27:10
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:27:10

US3542309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:26:12
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Jan 2021 22:32:19

US3542309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:26:12
User entered empty.	Hannah Yellin (b) (4) (b) (4)	29 Jan 2021 22:32:19

US3542309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:26:12
User entered empty.	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 22:32:19
	(b) (4)	

US3542309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:12
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:26:12
User entered empty.	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 22:32:19
	(b) (4)	

US3542309

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:26:12
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 22:32:25
	(b) (4)	

US3542309

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:48
User entered 'l'	System	29 Jan 2021 22:32:25

US3542309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:22

US3542309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:22

US3542309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:22

US3542309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4)	31 Mar 2021 19:51:22

US3542309

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 18:06:14

US3542309

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User entered 'l'	System	31 Mar 2021 18:06:14

US3542309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:18

US3542309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:18

US3542309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 19:51:18

US3542309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered empty.	(b) (4) Erika Faust (b) (4)	31 Mar 2021 19:51:18

US3542309

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 18:06:21

US3542309

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User entered 'l'	System	31 Mar 2021 18:06:21

US3542309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:32
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 18:06:45

US3542309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:32
User entered '30 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 18:06:45

US3542309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erika Faust (b) (4)	31 Mar 2021 18:06:45

US3542309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:32
User entered 'Left voicemails at 9:22, 11:09, 14:39'	(b) (4) Erika Faust (b) (4)	31 Mar 2021 18:06:45

US3542309

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 18:06:51

US3542309

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:13:21
User entered 'l'	System	31 Mar 2021 18:06:51

US3542309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:40

US3542309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:40

US3542309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:40

US3542309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 18:23:40

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:23:52

US3542309

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:09

US3542309

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:09

US3542309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:34

US3542309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:34

US3542309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered '11:09'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:34

US3542309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 11:09'	System	20 Apr 2021 18:24:34

US3542309

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Apr 2021 02:50:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:24:42

US3542309

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:24:42

US3542309

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:54:42

US3542309

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:54:42

US3542309

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:54:42

US3542309

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered 'UNBLND_DECIDE'	System	15 Mar 2021 16:54:42

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	15 Mar 2021 16:55:16

US3542309

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered empty.	System	15 Mar 2021 16:55:16

US3542309

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:26

US3542309

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:26

US3542309

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '11:08'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:26

US3542309

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '15 Mar 2021 11:08'	System	15 Mar 2021 16:55:26

US3542309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:37

US3542309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Mar 2021'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:55:37

US3542309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '11:10'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:55:37

US3542309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:17
User entered '15 Mar 2021 11:10'	System	15 Mar 2021 16:55:37

US3542309

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:11:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:59
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:58:28

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Nov 2020 18:00:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:00:20
Data point term sent to Coder	System	05 Nov 2020 17:59:26
User entered 'Headache'	Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '29 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User closed query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:05:33
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
Query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' answered with 'time is unknown' (Site from DM).	Elissa Malkin (b) (4)	11 Nov 2020 18:23:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 04:23:26
User opened query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:23:23
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Elissa Malkin (b) (4)	09 Nov 2020 21:18:07
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 17:59:05
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
User entered empty.	System	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '29 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User closed query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:05:48
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
Query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' answered with 'time is unknown' (Site from DM).	Elissa Malkin (b) (4)	11 Nov 2020 18:23:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 04:23:37
User opened query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. If the time is unknown, please try and provide your best estimation to the time. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:23:35
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Elissa Malkin (b) (4)	09 Nov 2020 21:18:18
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 17:59:05
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
User entered empty.	System	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 21:18:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:18:52
User entered 'Related (RELATED)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	09 Nov 2020 21:18:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 17:59:05
User entered empty.	System	05 Nov 2020 17:59:05
	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	09 Nov 2020 21:18:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:18:52
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	09 Nov 2020 21:18:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:59:05
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 21:18:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:18:52
User entered 'None (NONE)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	09 Nov 2020 21:18:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 17:59:05
User entered empty.	System	05 Nov 2020 17:59:05
	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	09 Nov 2020 21:19:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 17:59:05
User entered '0'	Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	09 Nov 2020 21:19:06
User entered '0'	(b) (4)	
	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
User entered '0'	System	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02
User entered '0'	System	05 Nov 2020 17:59:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Scalp laceration - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 22:25:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 22:25:55
Data point term sent to Coder	System	18 Nov 2020 20:21:29
User entered 'Posterior scalp laceration'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
User entered empty.	System	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:47:38
User entered 'No (N)' reason for change: New Information	(b) (4) Erika Faust (b) (4)	18 Dec 2020 15:47:38
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 15:47:38
User entered '17 Dec 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 15:47:38
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
User entered empty.	System	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'l'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'l'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 15:47:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 15:47:38
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
User entered '0'	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05
User entered 'I'	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Neurological disorders congenital, HLT: Cerebellar disorders congenital, PT: Arnold-Chiari malformation, LLT: Chiari malformation - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:23:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:23:50
Data point term sent to Coder	System	18 Nov 2020 20:22:31
User entered 'Chiari malformation'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

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Folder: Adverse Events

Form: Adverse Events (3)

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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)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:34
User entered 'USA-US084-2020-mRNA-1273-P301000005'	System	19 Nov 2020 14:17:26
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 14:17:26

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Subarachnoid haemorrhage, LLT: Subarachnoid hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:26:49
Data point term sent to Coder	System	18 Nov 2020 20:26:34
User entered 'Subarachnoid hemorrhage'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	17 Dec 2020 16:00:26
Signature has been broken.	System	17 Dec 2020 16:00:26
User entered 'No (N)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	17 Dec 2020 16:00:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Caroline Thoreson (b) (4)	17 Dec 2020 16:00:26
User signature succeeded.	(b) (4)	17 Dec 2020 15:58:12
User entered 'Yes (Y)'	System	17 Dec 2020 15:58:12
	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	21 Nov 2020 16:54:25
	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	17 Dec 2020 15:58:12
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 15:58:12
Signature has been broken.	Caroline Thoreson (b) (4)	17 Dec 2020 15:58:12
User entered '11 Dec 2020' reason for change: Per Query Resolution	(b) (4)	17 Dec 2020 15:58:12
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Caroline Thoreson (b) (4)	17 Dec 2020 15:57:52
User signature succeeded.	System	17 Dec 2020 15:57:52
User entered empty.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	18 Nov 2020 20:26:05
	Caroline Thoreson (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:33:09
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:31:43
User entered empty.	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
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)	18 Nov 2020 20:27:41
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	18 Nov 2020 20:27:41
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	18 Nov 2020 20:26:05
User entered 'I'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '15 Nov 2020' reason for change: Per Query Resolution	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:27:41
	(b) (4)	
	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'l'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:16:39
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Pt had MRI 11-DEC-20 which showed resolution of SAH. ' (Site from Safety).	Caroline Thoreson (b) (4) (b) (4)	17 Dec 2020 16:00:45
Signature has been broken.	Caroline Thoreson (b) (4) (b) (4)	17 Dec 2020 15:57:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4) (b) (4)	17 Dec 2020 15:57:52
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:31:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject had CT of Brain, CBC and CMP, EKG, US Carotid, TTE Doppler and MRI. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to the record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:30:52
Query 'Per DM CLR: Narrative indicates that the subject had CT of Brain, CBC and CMP, EKG, US Carotid, TTE Doppler and MRI. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to the record the procedures as appropriate. Otherwise, clarify.' answered with 'Added to con procedures.' (Site from DM).	David Diemert (b) (4)	05 Feb 2021 21:36:43
User opened query 'Per DM CLR: Narrative indicates that the subject had CT of Brain, CBC and CMP, EKG, US Carotid, TTE Doppler and MRI. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to the record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:03:50
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the CK level and were there any signs of renal insufficiency as a result.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:17:37
User closed query 'PV Query: Please consider adding congenital chiari malformation to medical history.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:17:33
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:17:24
User closed query 'PV Query: Was the subject taking any statins?' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:17:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
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 Dec 2020 21:17:00
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:16:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the CK level and were there any signs of renal insufficiency as a result.' answered with 'Updated and records sent to Safety Moderna.' (Site from Safety).	Caroline Thoreson (b) (4) (b) (4)	17 Dec 2020 16:53:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED SYNCOPAL EPISODE ON 13-NOV-2020. SHE REPORTS FEELING "LIGHTHEADEDNESS" AND "ROOM-SPINNING" WHILE STANDING AND PROCEEDED TO HAVE A FALL. SHE EXPERIENCED HEAD INJURY AND LOSS OF CONSCIOUSNESS. SUBJECT WAS TAKEN TO NEARBY ED AND FOUND TO HAVE ACUTE SUBARACHNOID HEMORRHAGE ON CT BRAIN WO CONTRAST. SARS-COV-2 TEST PERFORMED 13-NOV-20 WAS NOT DETECTED. CBC AND CMP WERE PERFORMED AND RELATIVELY UNREMARKABLE. TROPONIN WAS NEGATIVE. ETHANOL LEVEL WAS NEGATIVE. EKG SHOWED NSR. US CAROTID DUPLEX BILATERAL WAS NORMAL. TTE WITH DOPPLER SHOWED NORMAL LEFT AND RIGHT VENTRICULAR CHAMBER SIZE AND FUNCTION. NO EVIDENCE OF SIGNIFICANT VALVULAR DYSFUNCTION. EF 65-70%. NEUROLOGY AND NEUROSURGERY WERE CONSULTED AND SUBJECT WAS ADMITTED TO NEUROLOGY SERVICE FOR OBSERVATION. SUBJECT ALSO EXPERIENCED POSTERIOR SCALP LACERATION AS RESULT OF FALL. IN ADDITION, CT HEAD SHOWED CHIARI MALFORMATION (LIKELY CONGENITAL). SUBJECT WAS DISCHARGED ON 15-NOV-2020 AND IS SCHEDULED TO F/U WITH NEUROLOGY AND PCP. PMH INCLUDES IRON DEFICIENCY ANEMIA, ENVIRONMENTAL ALLERGIES, BENIGN BRAIN TUMOR (1999), UMBILICAL HERNIA REPAIR (1966) AND HYSTERECTOMY (2018). Participant had repeat MRI on 11-DEC-20 which showed resolution of SAH.'	Caroline Thoreson (b) (4) (b) (4)	17 Dec 2020 16:52:50

reason for change: Per Query Resolution

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED SYNCOPAL EPISODE ON 13-NOV-2020. SHE REPORTS FEELING "LIGHTHEADEDNESS" AND "ROOM-SPINNING" WHILE STANDING AND PROCEEDED TO HAVE A FALL. SHE EXPERIENCED HEAD INJURY AND LOSS OF CONSCIOUSNESS. SUBJECT WAS TAKEN TO NEARBY ED AND FOUND TO HAVE ACUTE SUBARACHNOID HEMORRHAGE ON CT BRAIN WO CONTRAST. SARS-COV-2 TEST PERFORMED 13-NOV-20 WAS NOT DETECTED. CBC and CMP were performed and relatively unremarkable. Troponin was negative. Ethanol level was negative. EKG showed NSR. US carotid duplex bilateral was normal. TTE with doppler showed normal left and right ventricular chamber size and function. No evidence of significant valvular dysfunction. EF 65-70%. NEUROLOGY AND NEUROSURGERY WERE CONSULTED AND SUBJECT WAS ADMITTED TO NEUROLOGY SERVICE FOR OBSERVATION. SUBJECT ALSO EXPERIENCED POSTERIOR SCALP LACERATION AS RESULT OF FALL. IN ADDITION, CT HEAD SHOWED CHIARI MALFORMATION (LIKELY CONGENITAL). SUBJECT WAS DISCHARGED ON 15-NOV-2020 AND IS SCHEDULED TO F/U WITH NEUROLOGY AND PCP. PMH INCLUDES IRON DEFICIENCY ANEMIA, ENVIRONMENTAL ALLERGIES, BENIGN BRAIN TUMOR (1999), UMBILICAL HERNIA REPAIR (1966) AND HYSTERECTOMY (2018).'	Caroline Thoreson (b) (4)	17 Dec 2020 16:52:16
reason for change: Per Query Resolution Query 'PV Query: Please consider adding congenital chiari malformation to medical history.' answered with 'Chiari malformation was added as an AE as the diagnosis occurred after date of ICF.' (Site from Safety).	Caroline Thoreson (b) (4)	17 Dec 2020 16:42:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'PMH includes iron deficiency anemia, environmental allergies, benign brain tumor (1999), umbilical hernia repair (1966) and hysterectomy (2018).' (Site from Safety). User entered 'PATIENT EXPERIENCED SYNCOPAL EPISODE ON 13-NOV-2020. SHE REPORTS FEELING "LIGHTHEADEDNESS" AND "ROOM-SPINNING" WHILE STANDING AND PROCEEDED TO HAVE A FALL. SHE EXPERIENCED HEAD INJURY AND LOSS OF CONSCIOUSNESS. SUBJECT WAS TAKEN TO NEARBY ED AND FOUND TO HAVE ACUTE SUBARACHNOID HEMORRHAGE ON CT BRAIN WO CONTRAST. SARS-COV-2 TEST PERFORMED 13-NOV-20 WAS NOT DETECTED. NEUROLOGY AND NEUROSURGERY WERE CONSULTED AND SUBJECT WAS ADMITTED TO NEUROLOGY SERVICE FOR OBSERVATION. SUBJECT ALSO EXPERIENCED POSTERIOR SCALP LACERATION AS RESULT OF FALL. IN ADDITION, CT HEAD SHOWED CHIARI MALFORMATION (LIKELY CONGENITAL). SUBJECT WAS DISCHARGED ON 15-NOV-2020 AND IS SCHEDULED TO F/U WITH NEUROLOGY AND PCP.	Caroline Thoreson (b) (4)	17 Dec 2020 16:42:24
PMH includes iron deficiency anemia, environmental allergies, benign brain tumor (1999), umbilical hernia repair (1966) and hysterectomy (2018).' reason for change: Per Query Resolution		
Query 'PV Query: Was the subject taking any statins?' answered with 'No' (Site from Safety). Signature has been broken.	Caroline Thoreson (b) (4)	17 Dec 2020 16:02:54
	Caroline Thoreson (b) (4)	17 Dec 2020 16:02:39

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED SYNCOPAL EPISODE ON 13-NOV-2020. SHE REPORTS FEELING "LIGHTHEADEDNESS" AND "ROOM-SPINNING" WHILE STANDING AND PROCEEDED TO HAVE A FALL. SHE EXPERIENCED HEAD INJURY AND LOSS OF CONSCIOUSNESS. SUBJECT WAS TAKEN TO NEARBY ED AND FOUND TO HAVE ACUTE SUBARACHNOID HEMORRHAGE ON CT BRAIN WO CONTRAST. SARS-CoV-2 test performed 13-NOV-20 was not detected. NEUROLOGY AND NEUROSURGERY WERE CONSULTED AND SUBJECT WAS ADMITTED TO NEUROLOGY SERVICE FOR OBSERVATION. SUBJECT ALSO EXPERIENCED POSTERIOR SCALP LACERATION AS RESULT OF FALL. IN ADDITION, CT HEAD SHOWED CHIARI MALFORMATION (LIKELY CONGENITAL). SUBJECT WAS DISCHARGED ON 15-NOV-2020 AND IS SCHEDULED TO F/U WITH NEUROLOGY AND PCP.' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	17 Dec 2020 16:02:39
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 'SARS-CoV-2 test performed during admission on 13-NOV-20 was not detected. This result was faxed to Safety Moderna (part of medical records) on 17-DEC-20.' (Site from Safety).	Caroline Thoreson (b) (4)	17 Dec 2020 16:02:01
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Medical records faxed on 17-DEC-20' (Site from Safety).	Caroline Thoreson (b) (4)	17 Dec 2020 16:01:01
User opened query 'PV Query: Please consider adding congenital chiari malformation to medical history.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:32:24

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the subject taking any statins?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:32:18
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:32:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:32:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the CK level and were there any signs of renal insufficiency as a result.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:31:24
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)	25 Nov 2020 19:31:07
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Patient experienced syncopal episode on 13-NOV-2020. She reports feeling "lightheadedness" and "room-spinning" while standing and proceeded to have a fall. She experienced head injury and loss of consciousness. Subject was taken to nearby ED and found to have acute subarachnoid hemorrhage on CT brain w/o contrast. Neurology and neurosurgery were consulted and subject was admitted to neurology service for observation. Subject also experienced posterior scalp laceration as result of fall. In addition, CT head showed chiari malformation (likely congenital). Subject was discharged on 15-NOV-2020 and is scheduled to f/u with neurology and PCP.'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 20:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 20:28:59
Data point term sent to Coder	System	18 Nov 2020 20:27:36
User entered 'Syncope'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
User entered empty.	System	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:03
User entered 'Yes (Y)'	(b) (4)	
	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	18 Nov 2020 20:29:03
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 20:29:03
User entered '13 Nov 2020' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:03
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 20:26:49
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
User entered empty.	System	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'l'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
User entered '0'	System	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10
User entered 'I'	System	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:21:10

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 16:58:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 16:58:57
Data point term sent to Coder	System	15 Mar 2021 16:57:52
User entered 'Insomnia'	Erika Faust (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '15 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 16:57:24

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 01:15:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 01:15:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:19:45
Data point term sent to Coder	System	15 Mar 2021 16:58:53
User entered 'Shingles (Left flank)'	Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '25 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User entered empty.	System	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '07 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User entered empty.	System	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User entered '0'	System	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55
User entered 'I'	System	15 Mar 2021 16:58:20

US3542309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:11:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:36:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:38:24

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

Name of Medication

Audit	User	Time (GMT)
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: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:11:46
Data point term sent to Coder Coding entries removed.	System	17 Feb 2021 14:34:54
	David Diemert (b) (4)	17 Feb 2021 14:34:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
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: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 17:40:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 17:40:46
Data point term sent to Coder	System	02 Oct 2020 17:39:40
User entered 'Loratadine'	Erika Faust (b) (4)	02 Oct 2020 17:39:03
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:31:16
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Reconcile with MH entry so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 08:46:03
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Reconcile with MH entry so there is an appropriate match. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	17 Feb 2021 14:34:34
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	17 Feb 2021 14:34:27
Signature has been broken.	David Diemert (b) (4) (b) (4)	17 Feb 2021 14:34:27
User entered 'ALLERGIES (environmental)' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	17 Feb 2021 14:34:27
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Reconcile with MH entry so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 23:57:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:47:01
User entered 'Allergies'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	18 Nov 2020 14:47:41
	(b) (4)	
User entered '10' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	18 Nov 2020 14:47:41
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered '1'	Erika Faust (b) (4)	02 Oct 2020 17:39:03
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	18 Nov 2020 14:47:41
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	18 Nov 2020 14:47:41
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'tablet (TABLET)'	Erika Faust (b) (4)	02 Oct 2020 17:39:03
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'as needed (PRN)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'UN UNK 2018'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:29:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:29:21
Data point term sent to Coder	System	05 Nov 2020 16:28:04
User entered 'Tylenol'	Erika Faust (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Headache'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '325'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '29 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered '29 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
User entered empty.	System	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
User entered empty.	System	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:02
User entered empty.	System	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 03:55:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:55:53
Data point term sent to Coder	System	18 Nov 2020 20:11:16
User entered 'Lidocaine (1%)'	Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Posterior scalp laceration'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '5'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mL (mL)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'once (ONCE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Other (OTHER)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Intradermal'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
User entered empty.	System	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
User entered empty.	System	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:51
User entered empty.	System	18 Nov 2020 20:10:59

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 04:22:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 04:22:55
Data point term sent to Coder	System	18 Nov 2020 20:12:18
User entered 'Enoxaparin'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'DVT prophylaxis'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:31:16
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 08:46:36
DataPoint Un-verified.	David Diemert (b) (4)	17 Feb 2021 14:39:07
Signature has been broken.	(b) (4)	
User entered '30' reason for change: Per Query Resolution	David Diemert (b) (4)	17 Feb 2021 14:39:01
DataPoint Verified.	(b) (4)	
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	(b) (4), (b) (6)	18 Dec 2020 18:55:18
User entered '3'	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:31:16
DataPoint Un-verified.	David Diemert (b) (4)	17 Feb 2021 14:39:01
Signature has been broken.	David Diemert (b) (4)	17 Feb 2021 14:39:01
User entered 'mg (mg)' reason for change: Per Query Resolution	David Diemert (b) (4)	17 Feb 2021 14:39:01
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mL (mL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'twice daily (BID)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '15 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
User entered '2'	System	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
User entered '1'	System	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:28
User entered '804 (804)'	System	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 08:46:41
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' answered with 'The participant was given a dose of TdAP less than 28 days after her second dose of IP/placebo upon admission to hospital. A protocol deviation has been recorded.' (Site from DM).	David Diemert (b) (4)	17 Feb 2021 14:45:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:31:42
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 20:13:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 20:13:59

PRODUCTION RELEASE (v12.003
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US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Nov 2020 20:13:21
User entered 'Tdap vaccine'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Tetanus prophylaxis'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0.5'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mL (mL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'once (ONCE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
User entered empty.	System	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
User entered empty.	System	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:43
User entered empty.	System	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:55:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:55:53
Data point term sent to Coder	System	18 Nov 2020 20:14:22
User entered 'Levetiracetam'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Subarachnoid hemorrhage'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '500'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'twice daily (BID)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '14 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:29:48
Data point term sent to Coder	System	18 Nov 2020 20:14:22
User entered 'Acetaminophen'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Subarachnoid hemorrhage'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '650'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'other (OTHER)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'q6h prn'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '14 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 12:04:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 12:04:53
Data point term sent to Coder	System	18 Nov 2020 20:19:27
User entered 'Ibuprofen'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Subarachnoid hemorrhage'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '800'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'other (OTHER)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'q8h prn'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '14 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: TISSUE ADHESIVES, PRODUCT: OCRILATE, PRODUCTSYNONYM: DERMABOND - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:22:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:22:01
Data point term sent to Coder	System	18 Nov 2020 20:20:28
User entered 'Dermabond'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Posterior scalp laceration'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'unknown'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Other (OTHER)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'unknown'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'once (ONCE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Topical (TOPICAL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:14:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
User entered empty.	System	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
User entered empty.	System	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:55:52
User entered empty.	System	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Mar 2021 17:02:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 17:02:57
Data point term sent to Coder	System	15 Mar 2021 17:01:55
User entered 'Trazodone'	Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Insomnia'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	06 Apr 2021 15:07:27
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:24
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	05 Apr 2021 15:22:35
Signature has been broken.	David Diemert (b) (4) (b) (4)	05 Apr 2021 15:21:17
User entered '100' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	05 Apr 2021 15:21:17
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:28:28
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:19:45
User entered '10'	Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'other (OTHER)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Once every evening as needed'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '20 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:19:45
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 17:00:56

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:11:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:15:05
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:09:21

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:15:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '13 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:15:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Posterior scalp laceration repair'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:15:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Adverse Event (AE)'	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:06

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:15:13
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:09
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered '13 Nov 2020'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:38:00

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:09
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'CT Head & Cervical Spine'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:38:00

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:09
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:38:00

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:09
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered empty.	(b) (4) David Diemert (b) (4)	05 Feb 2021 21:38:00

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:12
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered '14 Nov 2020'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:08

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:12
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Carotid ultrasound, bilateral'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:08

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:12
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:08

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:12
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:08

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:17
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered '11 Dec 2020'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:30

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:17
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'MRI Brain'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:30

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:17
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:30

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:17
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:30

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:11:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:20
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered '15 Nov 2020'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:53

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:20
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Transthoracic echocardiogram with Doppler'	(b) (4) David Diemert (b) (4)	05 Feb 2021 21:39:53

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:20
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:53

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:20
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:01
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	05 Feb 2021 21:39:53

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'USA-US084-2020-MRNA-1273-P301000005'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'David'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Diemert'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '2300 Eye Street NW'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Washington'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Dec 2020 19:15:19
User entered empty.	System	17 Dec 2020 19:15:19
User signature succeeded.	System	17 Dec 2020 19:15:19
	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'DC'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '20037'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 19:15:11
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'US'	(b) (4) System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4)	
	System	17 Dec 2020 19:15:19
User entered '2'	System	17 Dec 2020 19:15:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'USA-US084-2020-MRNA-1273-P301000005'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'David'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Diemert'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '2300 Eye Street NW'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Washington'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Dec 2020 19:15:19
User entered empty.	System	17 Dec 2020 19:15:19
User signature succeeded.	System	17 Dec 2020 19:15:19
	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'DC'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '20037'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 19:15:11
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'US'	(b) (4) System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4)	
User entered '2'	System	17 Dec 2020 19:15:19
User signature succeeded.	System	17 Dec 2020 19:15:19
User entered '1'	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
	System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '19/Nov/2020 14:17'	(b) (4) System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 19:15:11
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'l'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'USA-US084-2020-MRNA-1273-P301000005'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'No (N)'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'David'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Diemert'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '2300 Eye Street NW'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'Washington'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Un-reviewed for Safety.	(b) (4)	17 Dec 2020 19:15:19
Signature has been broken.	System	17 Dec 2020 19:15:19
User entered empty.	System	17 Dec 2020 19:15:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered 'DC'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:17:53
User entered '20037'	System	19 Nov 2020 14:17:26

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 19:15:11
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'US'	(b) (4) System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
Signature has been broken.	(b) (4)	
	System	17 Dec 2020 19:15:19
User entered '2'	System	17 Dec 2020 19:15:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	System	19 Nov 2020 14:18:01

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered '17/Dec/2020 19:15'	(b) (4) System	17 Dec 2020 19:15:19

US3542309

Folder: SAE USA-US084-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:32:40
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:15:19