

US3542309 (Prod: George Washington University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:44

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US3542309

Form: Participant Creation

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

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

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

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Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

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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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3542309

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 26 Nov 2020 09:37:44

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

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

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

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Condition	ANEMIA (IRON DEFICIENCY)
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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: 26 Nov 2020 09:37:44

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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: 26 Nov 2020 09:37:44

Condition	BENIGN BRAIN TUMOR
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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: 26 Nov 2020 09:37:44

Condition	UMBILICAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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: 26 Nov 2020 09:37:44

Condition	ALLERGIES (ENVIRONMENTAL)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	1 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:33 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:33
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	161 lb
BMI (<i>xxx.x</i>)	25.26889 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

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

Generated On: 26 Nov 2020 09:37:44

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: Screening

Form: Childbearing Potential

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

Generated On: 26 Nov 2020 09:37:44

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

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 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: 26 Nov 2020 09:37:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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: 26 Nov 2020 09:37:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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) 03 Oct 2020 15:47:11

Generated On: 26 Nov 2020 09:37:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

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

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Was the sample collected?	Yes ☒
	No ☐
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: 26 Nov 2020 09:37:44

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		

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Folder: Visit 1 Day 1

Form: Continuing

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

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
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: 26 Nov 2020 09:37:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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: 26 Nov 2020 09:37:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Was the sample collected?	Yes ☒
	No ☐
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

100.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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 ☒

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

Yes ☐	
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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

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 _____

US3542309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3542309

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:44

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

Generated On: 26 Nov 2020 09:37:44

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3542309

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

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06 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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13 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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20 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

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27 JAN 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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10 FEB 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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10 MAR 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 166

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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17 NOV 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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: 26 Nov 2020 09:37:44

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

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29 JUN 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 JUL 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

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

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

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US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:37:44

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 AUG 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 SEP 2022 00:01

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07 SEP 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 SEP 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 SEP 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:37:44

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 ☐ 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: 26 Nov 2020 09:37:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:37:44

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3542309

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:37:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542309

Folder: Adverse Events

Form: Adverse Events Summary

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

Generated On: 26 Nov 2020 09:37:44

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)

Generated On: 26 Nov 2020 09:37:44

AEID	
Adverse event	HEADACHE
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☒ 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:37:44

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)	
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	
v6.020 DTW (1102)	
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US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:37:44

AEID	
Adverse event	CHIARI MALFORMATION
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)	
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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (4)

Generated On: 26 Nov 2020 09:37:44

AEID	USA-US084-2020-MRNA-1273-P30 1000005
Adverse event	SUBARACHNOID HEMORRHAGE
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)	
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	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

PATIENT EXPERIENCED
SYNCPAL 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. 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.

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)

Generated On: 26 Nov 2020 09:37:44

AEID	
Adverse event	SYNCOPE
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)	13 NOV 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 ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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: 26 Nov 2020 09:37:44

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) 21 Nov 2020 16:54:24

Generated On: 26 Nov 2020 09:37:44

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 26 Nov 2020 09:37:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 26 Nov 2020 09:37:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 26 Nov 2020 09:37:44

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROHYLAXIS

Dose per administration 3

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 26 Nov 2020 09:37:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 26 Nov 2020 09:37:44

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 26 Nov 2020 09:37:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 26 Nov 2020 09:37:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 26 Nov 2020 09:37:44

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 ☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 26 Nov 2020 09:37:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 26 Nov 2020 09:37:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

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

Generated On: 26 Nov 2020 09:37:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

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

Generated On: 26 Nov 2020 09:37:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	POSTERIOR SCALP LACERATION REPAIR	Adverse Event	

US3542309

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:44

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

US3542309

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:37:44

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) 21 Nov 2020 16:54:24

Generated On: 26 Nov 2020 09:37:44

SAEID	USA-US084-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3542309

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

Form: Safety Report Form (1)

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

Generated On: 26 Nov 2020 09:37:44

SAEID	USA-US084-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
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

Audit

US3542309 (Prod: George Washington University)

US3542309

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:44

[Participant ID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	01 Oct 2020 16:30:46
	(b) (4)	

US3542309

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4)	01 Oct 2020 16:30:46
	(b) (4)	

US3542309

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Oct 2020 16:30:46

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
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) (b) (4)	01 Oct 2020 16:27:45

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Age](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '57'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '57'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

Sex

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Female (F)'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Ethnicity](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Oct 2020 17:35:14

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Black](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
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 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

Unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:44

[Not reported](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:35:14
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Oct 2020 16:31:04

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Amendment 3 (3)'	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'No (N)'	Elissa Malkin (b) (4)	01 Oct 2020 16:31:04
	(b) (4)	

US3542309

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:31:14

US3542309

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	01 Oct 2020 16:31:14
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:35:19
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 1970'	Erika Faust (b) (4)	02 Oct 2020 17:36:22
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:36:22
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:36:22
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:36:22
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:36:22
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1970'	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:36:22

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

[Condition](#)

Audit	User	Time (GMT)
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.	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)	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 2018'	Erika Faust (b) (4)	02 Oct 2020 17:36:46
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:36:46
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 17:36:46
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 2018'	Erika Faust (b) (4)	02 Oct 2020 17:36:46
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:36:46
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 17:36:46

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

[Condition](#)

Audit	User	Time (GMT)
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.	(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 'Benign brain tumor'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 1999'	Erika Faust (b) (4)	02 Oct 2020 17:37:15
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:15
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 17:37:15
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:15
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1999'	System	02 Oct 2020 17:37:15

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

[Condition](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 1966'	Erika Faust (b) (4)	02 Oct 2020 17:37:41
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:41
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 17:37:41
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 1966'	Erika Faust (b) (4)	02 Oct 2020 17:37:41
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:41
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1966'	System	02 Oct 2020 17:37:41

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

[Condition](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 2018'	Erika Faust (b) (4)	02 Oct 2020 17:37:57
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:57
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:37:57
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:37:57
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:37:57
	(b) (4)	

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:37:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:39:57
	(b) (4)	

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:39:57
	(b) (4)	

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '12:33'	Erika Faust (b) (4)	02 Oct 2020 17:39:57
	(b) (4)	

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 12:33'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

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

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

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

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

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

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Route of measurement](#)

Audit	User	Time (GMT)
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 17:39:57
	(b) (4)	

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[If Other, specify](#)

Audit	User	Time (GMT)
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 17:39:57
	(b) (4)	

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Pulse \(xxx\)](#)

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

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:39:57

US3542309

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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) (b) (4)	02 Oct 2020 17:40:33

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
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 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'UN UNK 2018'	Erika Faust (b) (4)	02 Oct 2020 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:37:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:40:33
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

[Other](#)

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

[Specify](#)

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
User entered '1'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 17:41:12

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 17:41:12
	(b) (4)	

US3542309

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:44

[Specify](#)

Audit	User	Time (GMT)
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 17:41:12
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:29
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:29
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:29
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Oct 2020 17:25:29

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
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 17:35:32
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:44

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:35:32
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:35:32
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:44

[Liver Disease](#)

Audit	User	Time (GMT)
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 17:35:32
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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 17:35:32
	(b) (4)	
DataPoint set to visible.	System	01 Oct 2020 16:31:04

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered missing code ND - Not Done.	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered missing code ND - Not Done.	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Height](#)

Audit	User	Time (GMT)
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 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered missing code ND - Not Done.	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '12:33'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '98.0' F	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Oral (Oral)'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[If Other, specify](#)

Audit	User	Time (GMT)
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 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '55'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '17'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '132'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '82'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Height](#)

Audit	User	Time (GMT)
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 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:44

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered missing code ND - Not Done.	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '13:58'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '97.9' F	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Oral (Oral)'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[If Other, specify](#)

Audit	User	Time (GMT)
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 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '56'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '14'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '136'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '85'	Erika Faust (b) (4)	02 Oct 2020 17:43:46
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 17:43:46

US3542309

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:35:50
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:35:50
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '13:16'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 13:16'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Elissa Malkin (b) (4)	01 Oct 2020 17:25:51
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 17:25:51

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:41:44
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '1 Oct 2020'	Erika Faust (b) (4)	02 Oct 2020 17:41:44
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '12:48'	Erika Faust (b) (4)	02 Oct 2020 17:41:44
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4)	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:41:57
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered '12:49'	Erika Faust (b) (4)	02 Oct 2020 17:41:57
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
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 17:41:57
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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 17:41:57
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:41:57

US3542309

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:34:56
	(b) (4)	

US3542309

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 17:34:56

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:00:38
User entered 'No (N)'	System	01 Oct 2020 18:00:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:51:09
User entered 'Yes (Y)'	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:51:09
User entered '02 Oct 2020 01:51'	System	02 Oct 2020 05:51:09

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:51:40
User entered 'Yes (Y)'	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:51:40
User entered 'No (N)'	System	02 Oct 2020 21:51:40

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Oct 2020 17:55:38
User entered '03 Oct 2020 13:55'	System	03 Oct 2020 17:55:38

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:00
User entered 'No (N)'	System	04 Oct 2020 17:26:00

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:00
User entered 'No (N)'	System	04 Oct 2020 17:26:00

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:04
User entered 'Yes (Y)'	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:04
User entered 'No (N)'	System	05 Oct 2020 23:01:04

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:21:28
User entered 'Yes (Y)'	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:21:28
User entered '93.2'	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:21:28
User entered '06 Oct 2020 20:21'	System	07 Oct 2020 00:21:28

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:34:44
User entered 'Yes (Y)'	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:34:44
User entered 'No (N)'	System	08 Oct 2020 03:34:44

US3542309

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:09
User entered 'None (1)'	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:09
User entered 'No (N)'	System	01 Oct 2020 18:01:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Oct 2020 12:23:11
User entered 'No (N)'	System	02 Oct 2020 12:23:11

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:09
User entered 'None (1)'	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:09
User entered 'No (N)'	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:09
User entered 'No (N)'	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:09
User entered 'None (1)'	System	02 Oct 2020 21:52:09

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:18
User entered 'None (1)'	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:18
User entered 'No (N)'	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:18
User entered 'None (1)'	System	04 Oct 2020 17:26:18

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:19
User entered 'No (N)'	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:19
User entered 'No (N)'	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:19
User entered '05 Oct 2020 19:01'	System	05 Oct 2020 23:01:19

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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' User entered 'None (1)'	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:21:44
User entered '06 Oct 2020 20:21'	System	07 Oct 2020 00:21:44

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:00
User entered '07 Oct 2020 23:34'	System	08 Oct 2020 03:35:00

US3542309

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'None (0)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered 'No (N)'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 18:01:41
User entered '01 Oct 2020 14:01'	System	01 Oct 2020 18:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'None (0)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered 'No (N)'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Oct 2020 05:52:22
User entered '02 Oct 2020 01:52'	System	02 Oct 2020 05:52:22

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'None (0)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered 'No (N)'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Oct 2020 21:52:36
User entered '02 Oct 2020 17:52'	System	02 Oct 2020 21:52:36

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	03 Oct 2020 17:56:39
User entered 'None (0)'	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	03 Oct 2020 17:56:39
User entered 'No (N)'	System	03 Oct 2020 17:56:39

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'None (0)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered 'No (N)'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Oct 2020 17:26:43
User entered '04 Oct 2020 13:26'	System	04 Oct 2020 17:26:43

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	05 Oct 2020 23:01:41
User entered 'No (N)'	System	05 Oct 2020 23:01:41

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'None (0)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered 'No (N)'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Oct 2020 00:22:05
User entered '06 Oct 2020 20:22'	System	07 Oct 2020 00:22:05

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'None (0)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered 'No (N)'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Oct 2020 03:35:18
User entered '07 Oct 2020 23:35'	System	08 Oct 2020 03:35:18

US3542309

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	12 Oct 2020 19:36:44
	(b) (4)	

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
	(b) (4)	
User entered '9 Oct 2020'	Erika Faust (b) (4)	12 Oct 2020 19:36:44
	(b) (4)	

US3542309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	12 Oct 2020 19:36:44
	(b) (4)	

US3542309

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:10:57
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	12 Oct 2020 19:36:50
	(b) (4)	

US3542309

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 19:36:50

US3542309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:51:37

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	26 Oct 2020 18:38:43
	(b) (4)	

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
	(b) (4)	
User entered '23 Oct 2020'	Erika Faust (b) (4)	26 Oct 2020 18:38:43
	(b) (4)	

US3542309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	26 Oct 2020 18:38:43
	(b) (4)	

US3542309

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	26 Oct 2020 18:38:49
	(b) (4)	

US3542309

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 18:38:49

US3542309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	29 Oct 2020 16:28:02

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 16:28:54

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 16:29:52

US3542309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered '11:12'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:02:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Oct 2020 15:15:40

US3542309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 16:31:20

US3542309

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 16:31:35

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:38
User entered 'Yes (Y)'	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:38
User entered '96.2'	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:38
User entered '28 Oct 2020 13:30'	System	28 Oct 2020 17:30:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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). 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 '1'	Erika Faust (b) (4)	05 Nov 2020 16:30:25
	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: 26 Nov 2020 09:37:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 19:49:49
User entered 'No (N)'	System	30 Oct 2020 19:49:49

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:37:33
User entered 'Yes (Y)'	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:37:33
User entered 'No (N)'	System	01 Nov 2020 02:37:33

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:38
User entered 'Yes (Y)'	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:38
User entered '93.2'	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:38
User entered '01 Nov 2020 19:07'	System	02 Nov 2020 00:07:38

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:23:51
User entered 'Yes (Y)'	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:23:51
User entered '94.2'	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:23:51
User entered '02 Nov 2020 14:23'	System	02 Nov 2020 19:23:51

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:17
User entered 'Yes (Y)'	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:17
User entered '96.2'	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:17
User entered 'No (N)'	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:17
User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:17

US3542309

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:47
User entered 'None (1)'	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:47
User entered 'No (N)'	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:30:47
User entered 'No (N)'	System	28 Oct 2020 17:30:47

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	29 Oct 2020 21:59:39
User entered 'No (N)'	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	29 Oct 2020 21:59:39
User entered 'No (N)'	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Oct 2020 21:59:39
User entered '29 Oct 2020 17:59'	System	29 Oct 2020 21:59:39

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	30 Oct 2020 19:49:59
User entered 'None (1)'	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 19:49:59
User entered 'No (N)'	System	30 Oct 2020 19:49:59

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:37:45
User entered '31 Oct 2020 22:37'	System	01 Nov 2020 02:37:45

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:53
User entered 'None (1)'	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:53
User entered 'No (N)'	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:53
User entered 'No (N)'	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:53
User entered 'None (1)'	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:07:53
User entered '01 Nov 2020 19:07'	System	02 Nov 2020 00:07:53

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:11
User entered 'None (1)'	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:11
User entered 'No (N)'	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:11
User entered 'No (N)'	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:11
User entered 'None (1)'	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:11
User entered '02 Nov 2020 14:24'	System	02 Nov 2020 19:24:11

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:30
User entered 'None (1)'	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:30
User entered 'No (N)'	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:30
User entered 'No (N)'	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

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

Please select one response below

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:30
User entered 'None (1)'	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:30
User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:30

US3542309

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered 'None (0)'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered 'None (0)'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered 'None (0)'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered 'None (0)'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered 'No (N)'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Oct 2020 17:31:09
User entered '28 Oct 2020 13:31'	System	28 Oct 2020 17:31:09

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Oct 2020 22:00:12
User entered 'None (0)'	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	29 Oct 2020 22:00:12
User entered 'No (N)'	System	29 Oct 2020 22:00:12

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'None (0)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered 'No (N)'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Nov 2020 02:38:03
User entered '31 Oct 2020 22:37'	System	01 Nov 2020 02:38:03

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'None (0)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered 'No (N)'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:08:08
User entered '01 Nov 2020 19:08'	System	02 Nov 2020 00:08:08

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'None (0)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered 'No (N)'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 19:24:26
User entered '02 Nov 2020 14:24'	System	02 Nov 2020 19:24:26

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:45
User entered 'No (N)'	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 23:03:45
User entered '03 Nov 2020 18:03'	System	03 Nov 2020 23:03:45

US3542309

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	05 Nov 2020 16:25:38
	(b) (4)	

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '4 Nov 2020'	Erika Faust (b) (4)	05 Nov 2020 16:25:38
	(b) (4)	

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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 16:25:38

US3542309

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	05 Nov 2020 16:25:43
	(b) (4)	

US3542309

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:25:43

US3542309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:58:13

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:37
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:24
	(b) (4)	

US3542309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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)	18 Nov 2020 20:29:37
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.' answered by data change (Site from System).	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)	18 Nov 2020 20:29:24
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: 26 Nov 2020 09:37:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:37
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:43
	(b) (4)	

US3542309

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:29:43

US3542309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	05 Nov 2020 17:58:28
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Adverse event](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:37:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '29 Oct 2020'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '29 Oct 2020'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

End time (00:00-23:59)

Audit	User	Time (GMT)
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.'	Elissa Malkin (b) (4)	11 Nov 2020 18:23:56
answered with 'time is unknown' (Site from DM).	(b) (4)	
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
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	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 'Related (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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	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 'None (NONE)' reason for change: Per Elissa Malkin	(b) (4)	09 Nov 2020 21:18:52
Query Resolution	(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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[None](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	09 Nov 2020 21:19:06
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 17:59:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 17:59:05

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Adverse event](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	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: 26 Nov 2020 09:37:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	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: 26 Nov 2020 09:37:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	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: 26 Nov 2020 09:37:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:21:23
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Outcome](#)

Audit	User	Time (GMT)
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 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Narrative](#)

Audit	User	Time (GMT)
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)	

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:21:23

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User coded data point as SOC: Congenital, familial and genetic disorders, HLT: 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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[AE start 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: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Outcome](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[Narrative](#)

Audit	User	Time (GMT)
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 20:22:02
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:22:02

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Adverse event](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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 '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '15 Nov 2020' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	18 Nov 2020 20:27:41
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Outcome](#)

Audit	User	Time (GMT)
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 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
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 20:26:05
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Narrative](#)

Audit	User	Time (GMT)
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 wo 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

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:26:05

US3542309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Adverse event](#)

Audit	User	Time (GMT)
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

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:26:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	18 Nov 2020 20:29:03
	(b) (4)	
User entered 'Yes (Y)'	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: 26 Nov 2020 09:37:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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).	(b) (4)	18 Nov 2020 20:26:49
User entered empty.	System	18 Nov 2020 20:26:49
	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '1'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Narrative](#)

Audit	User	Time (GMT)
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 20:26:49
	(b) (4)	

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 20:26:49

US3542309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:26:49

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:11
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	02 Oct 2020 17:38:24
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
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.	(b) (4) 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) (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) (b) (4)	02 Oct 2020 17:39:03

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'Allergies'	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: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
Signature has been broken.	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: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
Signature has been broken.	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: 26 Nov 2020 09:37:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'UN UNK 2018'	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: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered '0'	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: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'Yes (Y)'	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: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:47:01
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	05 Nov 2020 16:27:42

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Headache'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'mg (mg)'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'once (ONCE)'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '29 Oct 2020'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:24:19
	(b) (4)	
User entered '29 Oct 2020'	Erika Faust (b) (4)	05 Nov 2020 16:27:42
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Posterior scalp laceration'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '5'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mL (mL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'once (ONCE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Other (OTHER)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Intradermal'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:10:59
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	18 Nov 2020 20:12:06

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	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: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'DVT prophylaxis'	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: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '3'	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: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mL (mL)'	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: 26 Nov 2020 09:37:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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 20:12:06
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'twice daily (BID)'	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: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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 20:12:06
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) 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: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:12:06
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	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: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	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: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '15 Nov 2020'	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: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (b) (4)	18 Nov 2020 20:13:59
Data point term sent to Coder	System	18 Nov 2020 20:13:21
User entered 'Tdap vaccine'	Caroline Thoreson (b) (4) (b) (4)	18 Nov 2020 20:12:44

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	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: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Tetanus prophylaxis'	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: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0.5'	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: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mL (mL)'	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: 26 Nov 2020 09:37:44

If dose unit is Other, specify

Audit	User	Time (GMT)
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 20:12:44
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'once (ONCE)'	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: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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 20:12:44
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:12:44
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	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: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	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: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	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: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	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: 26 Nov 2020 09:37:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Subarachnoid hemorrhage'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '500'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mg (mg)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

If dose unit is Other, specify

Audit	User	Time (GMT)
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 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'twice daily (BID)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '14 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:13:22
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:13:22

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (b) (4)	18 Nov 2020 20:14:00

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '650'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mg (mg)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

If dose unit is Other, specify

Audit	User	Time (GMT)
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 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'other (OTHER)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'q6h prn'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '14 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:14:00
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
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-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (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) (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) (b) (4)	18 Nov 2020 20:19:20

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Subarachnoid hemorrhage'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '800'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'mg (mg)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'other (OTHER)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'q8h prn'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '14 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:20
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[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: 26 Nov 2020 09:37:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
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) (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) (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) (b) (4)	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Posterior scalp laceration'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'unknown'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Other (OTHER)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'unknown'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'once (ONCE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Topical (TOPICAL)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

If route of administration is Other, specify

Audit	User	Time (GMT)
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 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '0'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:19:55
	(b) (4)	

US3542309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:19:55

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:37:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:09:21
	(b) (4)	

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered '13 Nov 2020'	Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44
	(b) (4)	

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Posterior scalp laceration repair'	Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44
	(b) (4)	

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
	(b) (4)	
User entered 'Adverse Event (AE)'	Caroline Thoreson (b) (4)	18 Nov 2020 20:09:44
	(b) (4)	

US3542309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
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 20:09:44
	(b) (4)	

US3542309

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

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:44

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '1'	(b) (4) System	19 Nov 2020 14:18:01

US3542309

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

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:44

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '1'	(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: 26 Nov 2020 09:37:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:37:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:25
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:18:01